TCM4/40 operator’s manual

TCM4/40
operator's
manual

TCM4/40 monitoring systems

Operator's manual

From software version 3.0

CE 0459

RADIOMETER

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Contents

1. Introduction

Names, intended use and limitations

Proprietary names TCM4 monitor and TCM40 monitor.

Common names Transcutaneous pCO_2/pO_2 monitoring system (TCM4) and Transcutaneous $pCO_2/pO_2/SpO_2$/Pulse monitoring system (TCM40)

TCM4 series monitors The TCM4 and TCM40 monitoring systems are part of the TCM4 Series monitoring system.

Reference This operator's manual for the TCM4/40 monitoring systems is intended for use as a reference. It provides detailed operating instructions and answers to relevant questions about your monitoring systems.

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Intended use The TCM4 monitoring system is intended for continuous transcutaneous monitoring of carbon dioxide ($tcpCO_2$) and oxygen ($tcpO_2$) partial pressures. It is indicated for use on neonates, pediatrics, and adults not under gas anesthesia.

The TCM40 monitoring system is intended for continuous transcutaneous monitoring of carbon dioxide ($tcpCO_2$) and oxygen ($tcpO_2$) partial pressures as well as of oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate. It is indicated for use on neonates, pediatrics and adults not under gas anesthesia.

Sensors The sensors are provided non-sterile and are intended for reuse.

For information on site locations, see the relevant section about application of sensors in chapter 6 *In vivo monitoring*.

Environment of use In hospital/clinical environment.

Operator profile Only trained health care personnel are permitted to use the monitor.

Limitations Transcutaneous monitoring is intended only as an adjunct in patient assessment and must be used in conjunction with clinical signs and symptoms.

WARNING – *Risk of incorrect measurements*
$tcpCO_2/tcpO_2$ monitoring should not be used on patients in a compromised hemodynamic state as this may cause incorrect measurements.

WARNING – *Risk of incorrect measurements*
The DS100A SpO_2 sensor is contraindicated for use on active patients or for prolonged use. It is not designed for long-term monitoring. Using this sensor for long-term monitoring may result in incorrect measurements.

Continued on next page

Names, intended use and limitations, *Continued*

Limitations *(continued)*

WARNING – *Risk of allergic reactions*
The OXIband A/N and P/I SpO_2 sensors are contraindicated for use on patients who exhibit allergic reactions to the pressure-sensitive adhesive on the wraps.

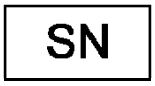
CAUTION – *US federal law restriction*
Federal law restricts this device to sale by or on the order of a physician.

NOTICE: This equipment is not a blood gas device.

Legal notices

- Instruments should be repaired by authorized service personnel or by Radiometer-certified representatives only.
- Purchase of the TCM40 monitoring system confers no express or implied license under any Nellcor patent to use this instrument with any oximetry sensor that is not manufactured or licensed by Nellcor.

Symbols used on the monitor

Symbol	Explanation
	CSA approved
	Caution, consult accompanying documents
	Temperature limitation
	Indicates that the product complies with the requirements of the Medical Device Directive 93/42/EEC June 1993. This product is a class IIa device.
	Serial number
	Non-ionizing radiation
	Type BF equipment (body floating)
	Manufacturer
	USB
	**Waste of Electrical and Electronic Equipment (WEEE)** The symbol indicates that: • Radiometer Medical ApS and its distributors within the European Union (EU) and associated states have taken the necessary steps to comply with the directive 2002/96/EC on waste electrical and electronic equipment (WEEE) • The instrument, when reaching its end of life, must be collected and recycled separately from other waste according to national requirements. Please contact your local Radiometer distributor for instructions. Environmental implications: WEEE contains materials that are potentially hazardous to the environment and to human health.

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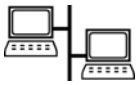
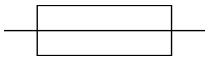
Symbols used on the monitor, *Continued*

Symbol	Explanation
	COM gate
	Ethernet interface connection to network. Not for phone connection.
	Off (Power: disconnection from the mains)
	On (Power: connection to the mains)
	Monitor on/off
	Fuse

Symbols used in the manual

This manual contains alerts, which are important and should be read carefully before performing the related procedures. The manual also contains non-safety information.

Symbol	Signal word	Explanation
	WARNING	A warning alerts the reader about a situation which, if not avoided, could result in death or serious injury. It may also describe potential serious adverse reactions and safety hazards.
	CAUTION	A caution alerts the reader about a potentially hazardous situation which, if not avoided, may result in minor or moderate injury to the user or the patient or damage to the equipment or other property. It may also be used to alert against unsafe practices. This includes the special care necessary for the safe and effective use of the device and the care necessary to avoid damage to the device that may occur as a result of use or misuse.
	NOTICE	Addresses practical information that is not related to personal injury ("need-to-know information").
		Manufacturer
		Indicates that the product complies with the requirements of the Medical Device Directive 93/42/EEC June 1993. This product is a class IIa device.

2. What is what

TCM4/40 monitoring systems

Introduction

The TCM4 monitoring system includes:

- Base unit
- tc*p*CO_2/tc*p*O_2 module
- Combined tc*p*CO_2/tc*p*O_2 sensors or single tc*p*CO_2 sensor

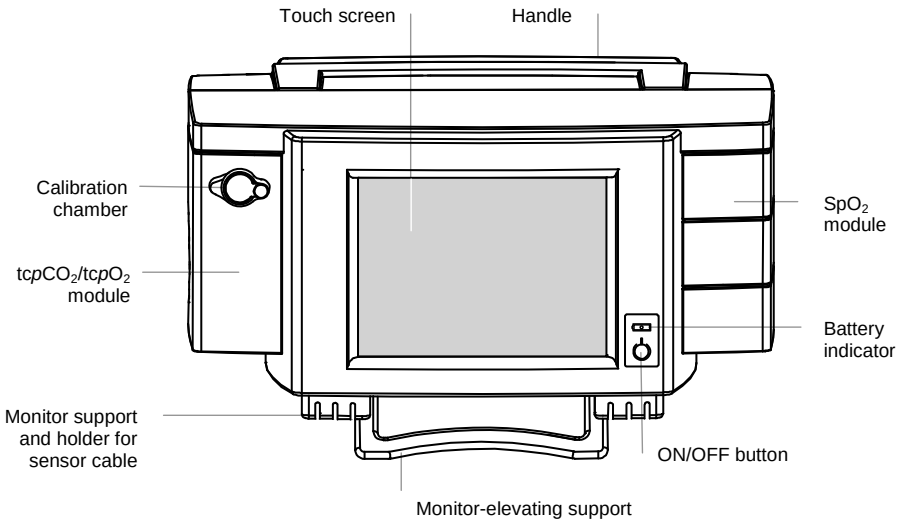
The TCM40 monitoring system includes:

- Base unit
- tc*p*CO_2/tc*p*O_2 module and SpO_2 module
- Sensors for tc*p*CO_2/tc*p*O_2 module: Combined tc*p*CO_2/tc*p*O_2 sensors or single tc*p*CO_2 sensor
- Sensors for SpO_2 module: SpO_2 sensors (Nellcor DS100A, Nellcor Oxiband A/N or Nellcor Oxiband P/I)

NOTICE: For ordering information, see the section *Accessories* in chapter 8.

Monitor – top and front

Front view

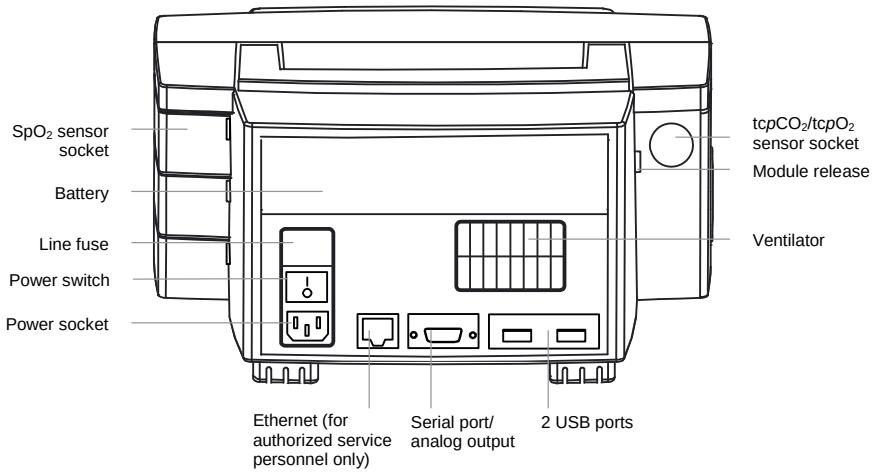


Parts and functions

Part	Function
Handle	For carrying the monitor.
Touch screen	For easy communication between operator and monitor.
Calibration chamber	For storage and calibration of tcpCO_2/tcpO_2 sensor.
tcpCO_2/tcpO_2 module	For transcutaneous measurements of tcpCO_2 and tcpO_2 and calibration of the sensor.
Monitor support and holder for sensor cable	For supporting the monitor and holding the sensor cable.
Monitor-elevating support	For supporting the monitor at an elevated angle.
⏻ ON/OFF button	For turning the monitor ON and OFF.
Battery indicator	For indicating whether the battery is being recharged or not. If the light is on, the battery is being recharged. **NOTICE:** Only possible if the power switch on the back of the monitor is in the ON position.
SpO_2 module (TCM40 monitor only)	For measurements of SpO_2 and pulse rate.

Monitor – rear

Rear view



Parts and functions

Part	Function
Battery	For allowing monitoring during transport and power failure.
SpO_2 sensor socket (TCM40 monitor only)	For connecting an SpO_2 sensor to the monitor.
Line fuse	1.25 AT. For preventing a short circuit. **WARNING – *Risk of fire*** Replace fuse only as recommended by Radiometer. Otherwise you risk that the monitor catches fire.
Power socket	For connecting a power cord to the monitor.
Serial port (RS232)	For connecting the monitor to an external computer.
Analog output	For connecting the monitor to a peripheral device such as a polysomnograph.
USB ports	For connecting the monitor to an external printer and a memory stick. **NOTICE:** It is only possible to use one of the ports at a time.
Module release	For releasing the sensor module from the monitor with a release key.
tc*p*CO_2/tc*p*O_2 sensor socket	For connecting a tc*p*CO_2/tc*p*O_2 sensor to the monitor.
Power switch	For turning the power supply to the monitor ON and OFF. **NOTICE:** If the power supply is ON, the battery will be recharged when needed.

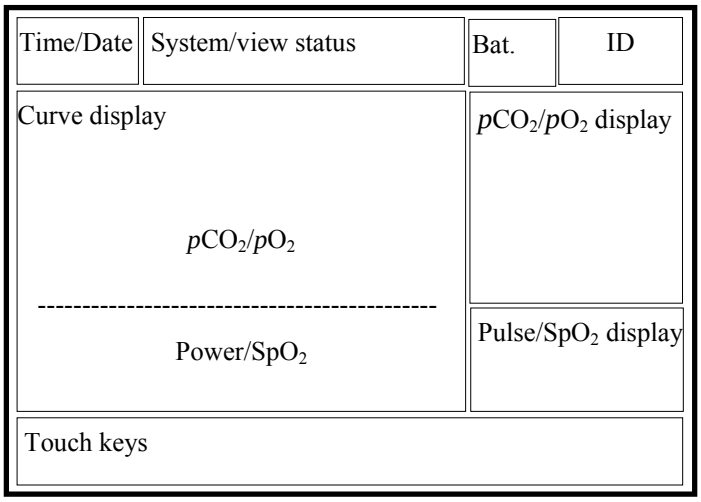
The screen: general elements

Screen types

There are two types of screens on the TCM4/40 monitors: view (i.e. Normal, Trend table and Trend Curve) and menu screens.

View screen configuration

The view screens are divided into the following fields:



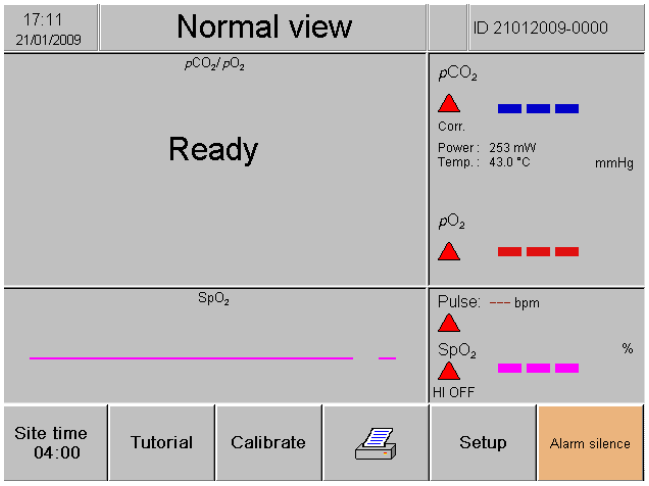
NOTICE: SpO_2 and pulse rate are available on the TCM40 monitor only. On the TCM4 monitor, the lower part of the curve display will either show the power curve or be empty, and the Pulse/SpO_2 display will always be empty (see examples on next page).

Part	Shows
Time and date	The real time (24-hour cycle) and date
System/view status	Normal view, Trend table view, Trend curve view, New patient, Alert or Alarm
Bat.	The battery level when the monitor is running on battery. Full, almost full, low and critically low
ID	Patient identification number. Gives access to Patient DMS.
Curve display	TCM4 monitor: pCO_2, pO_2 and power TCM40 monitor: pCO_2, pO_2 and SpO_2 Sensor status (e.g. Calibrating) and gas level (only displayed during calibration and if there is 10 % or less gas left in the gas cylinder). Barometric pressure (only displayed during calibration).
pCO_2/pO_2 display	pCO_2, pO_2, Corr., Power, Temp, SmartHeat, In vivo calibration active, (alarm is ON) and (alarm is OFF)
Pulse/SpO_2 display	Pulse, SpO_2, "HI OFF" (SpO_2 alarm high is disabled), (alarm is ON) and (alarm is OFF)

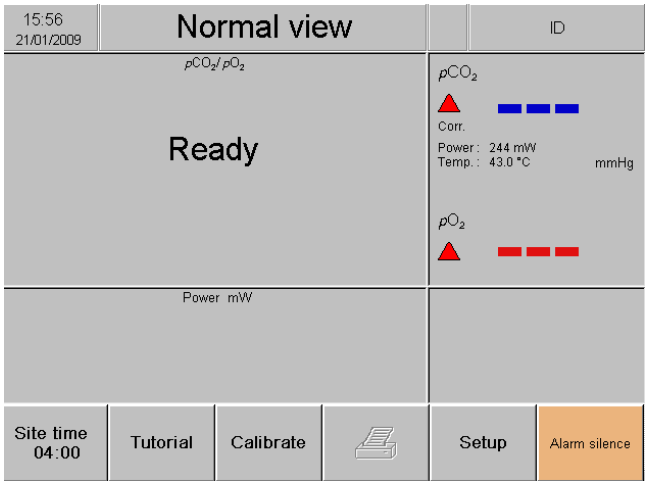
Continued on next page

The screen: general elements, *Continued*

Example of Normal view screen on TCM40 monitor



Example of Normal view screen on TCM4 monitor



NOTICE: In Measuring mode, the ***Event*** touch key replaces the ***Tutorial*** key.

Touch keys in Normal view

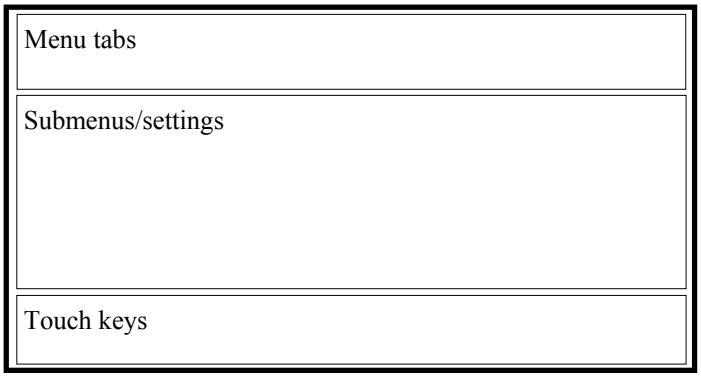
Touch key	Function
ID	Gives access to Patient DMS.
Site time xx:xx	Resets the site timer to its preset value (see Parameter setup).
Tutorial	Gives access to instruction videos – when not monitoring.
Event	Marks an event during monitoring.
Calibrate	Starts a calibration of the sensor (and the SmartCal period, if the function is set to ON in the setup).
Print	Gives access to the Printer start/stop time screen.
Setup	Gives access to all the setup menus and submenus.
Alarm silence	Silences/resets the alarm system.

Continued on next page

The screen: general elements, *Continued*

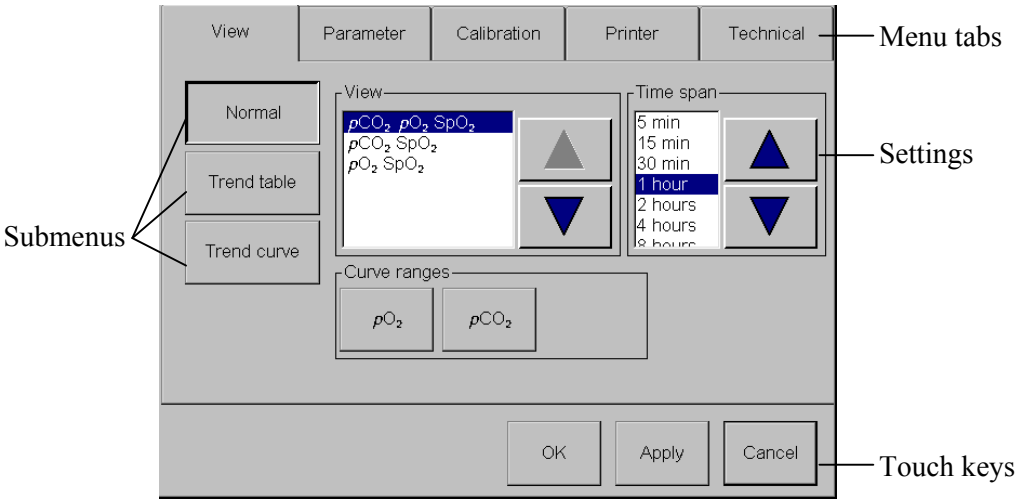
Menu screen configuration

The menu screens are divided into the following fields:



The menu screens contain the following tabs, which give access to the setup menus and submenus: View, Parameter, Calibration, Printer and Technical (password protected).

Example of menu screen



NOTICE: SpO_2 is available on the TCM40 monitor only.

Menu screen touch keys

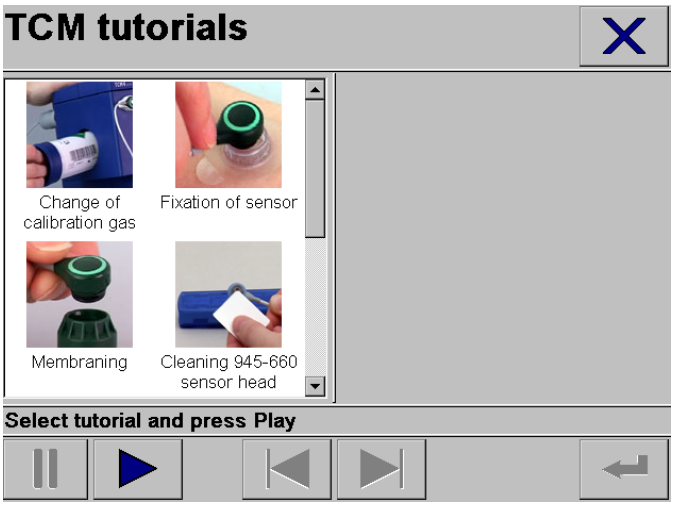
Touch key	Function
OK	Accepts the changes and returns to the main screen.
Apply	Accepts the changes without leaving the menu screen.
Cancel	Returns to the main screen without saving changes.

Online tutorials

Tutorials

The tutorials are short video sequences of commonly used procedures. To access the tutorials, press ***Tutorial***.

NOTICE: In Measuring mode, the ***Event*** touch key replaces the ***Tutorial*** key.



NOTICE: The DS100A sensor tutorial can only be selected on the TCM40 monitor.

Touch keys

Touch key	Function
	Pauses the selected tutorial.
	Plays the selected tutorial.
 and 	Scroll backward/forward one step in the selected tutorial.
	Returns to the TCM tutorials screen.
	Exits the tutorial and returns to Normal view.

Touch key glossary

Touch keys

In the text, touch keys are written in ***bold italic*** throughout the manual.

The glossary of all the touch keys used in the software with their description is given in alphabetical order in the table below:

Touch key	Function
	Adds a check mark to the highlighted patient ID/session number (in Patient DMS).
	Displays detailed information about the highlighted patient ID/session number (in Patient DMS).
Alarm silence	Silences/resets the alarm system.
Apply	Accepts the changes made in the settings without leaving the respective menu screen.
Blood gas	Gives access to the Blood gas setup where blood gas values can be keyed in.
Cal. status	Gives information about the last calibration.
Calibrate	Starts a calibration of the electrode.
Cancel	Returns to the main screen without saving the changes made in the settings.
Cursor	Adds/removes a cursor in the Trend curve view.
Date/time	Gives access to the Date/time setup (password protected).
Default values	Changes all settings to Radiometer default values (password protected).
Delete config. file	Part of the Service setup (only for service purposes).
Enter	Registers the entered password.
Event	Marks an event during monitoring.
Export	Exports the patient information and measuring data for the patient IDs/session numbers with a check mark (in Patient DMS).
ID	Gives access to Patient DMS.
In vivo calibration	Starts an in vivo calibration, i.e. a correction of the measured tc*p*CO_2/tc*p*O_2 values with the keyed-in blood gas values.
Normal	Gives access to the Normal view setup.

Continued on next page

Touch key glossary, *Continued*

Touch keys *(continued)*

Touch key	Function
OK	Accepts the changes made in the settings and returns to the main screen.
***p*CO$_2$**	In the Parameter menu, it gives access to the *p*CO$_2$ parameter setup. In the Trend curve setup, it gives access to the *p*CO$_2$ curve range screen.
***p*O$_2$**	In the Parameter menu, it gives access to the *p*O$_2$ parameter setup. In the Trend curve setup, it gives access to the *p*O$_2$ curve range screen.
Power	Gives access to the Power range screen.
Print	Gives access to the Printer start/stop time screen.
Service menu	Gives access to the Service setup (password protected).
Setup	Gives access to all the Setup menus.
Site time	Resets the site timer to its preset value (see Parameter setup).
SmartCal	Keeps the electrode ready for use (i.e. calibrated for max. 12 hours).
SpO$_2$*/Pulse*	In the Parameter menu, it gives access to the SpO$_2$/Pulse parameter setup. In the Trend curve setup, it gives access to the SpO$_2$/Pulse curve range screen.
System info	Part of the Service setup (only for service purposes).
Tech. settings	Gives access to the Technical settings (password protected).
Test	Part of the Service setup (only for service purposes).
Touch screen calibration	Part of the Service setup (only for service purposes).
Trend curve	Gives access to the Trend curve setup.
Trend table	Gives access to the Trend table setup.
Tutorial	Gives access to instruction videos.

Continued on next page

Touch key glossary, *Continued*

Arrow touch keys

Touch key	Function
 or 	Changes the settings of the highlighted option.
 or 	Scrolls the displayed screen/parameters upward or downward.
 or 	Scrolls the displayed screen/parameters forward or backward.
	Scrolls quickly to the most recent result.
	Deletes one character at a time.
<< or >>	Moves one character at a time to the left or the right.

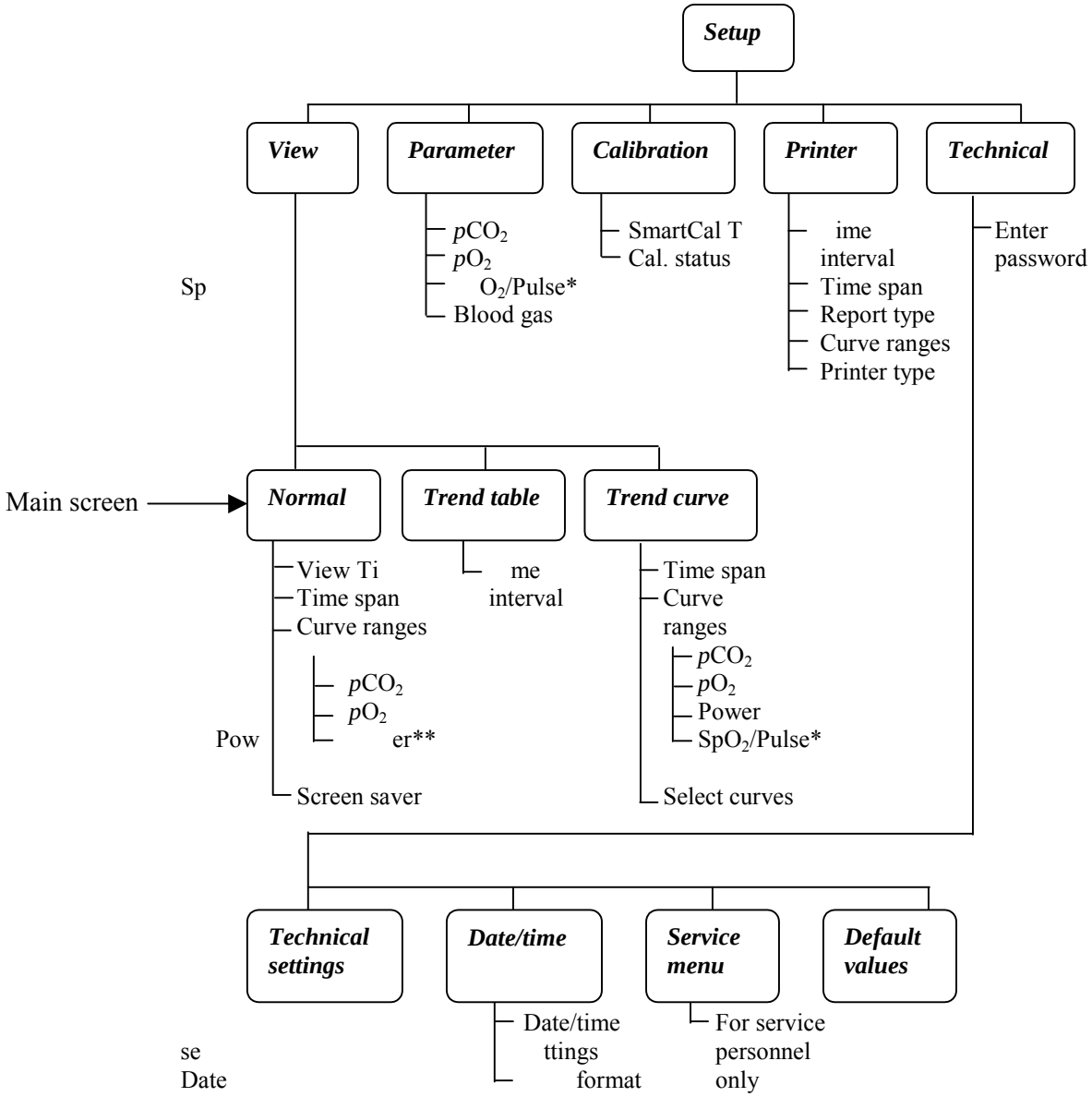
Tutorial touch keys

Touch key	Function
	Pauses the selected tutorial.
	Plays the selected tutorial.
 and 	Scroll backward/forward one step in the selected tutorial.
	Returns to the TCM Tutorials screen.
	Exits the tutorial and returns to Normal view.

3. Menu structure and setup programs

Menu structure

Menu structure The following diagram illustrates the menu structure of the TCM4/40 monitors.



* Available on the TCM40 monitor only.

** Available on the TCM4 monitor only.

NOTICE: If no touch key is activated for 30 seconds, the main screen (Normal view) is displayed.

List of setup programs

Accessing the Setup menus

Press the ***Setup*** touch key to get access to the Setup menus:

- View
- Parameter
- Calibration
- Printer
- Technical

Detailed information about the five main Setup menus is given in the following sections.

View setup

Normal view

Introduction

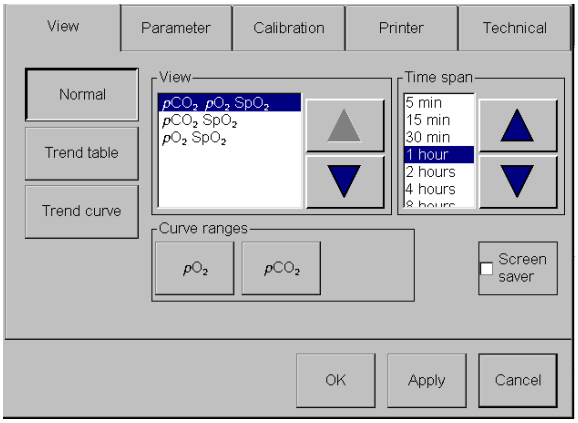
In the Normal view setup, it is possible to select which parameters will be shown in Normal view, to set the time span of the graphical display and to activate the screen saver.

NOTICE: If no touch key is activated for 30 seconds, the main screen (Normal view) is displayed.

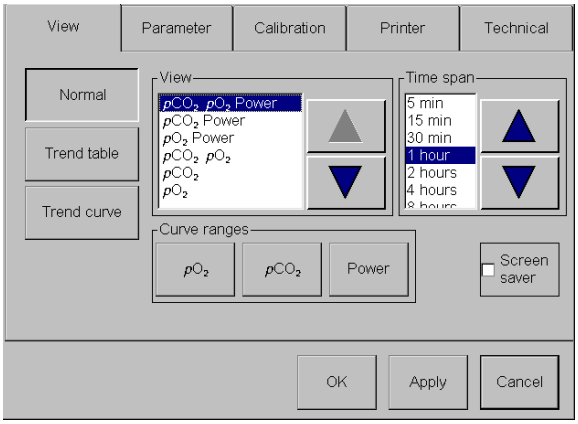
Accessing the program

To access the Normal view setup, press ***Setup*** → ***Normal***.

Normal view setup on TCM40 monitor:



Normal view setup on TCM4 monitor:



Selecting Normal view options

Step	Action
1.	Use the ***Up*** and ***Down*** arrows to select the curves that are to be shown in the curve area in Normal view. **NOTICES:** • Parameter values will always be shown. • The number of parameters to choose from depends on the sensor type installed (combined pCO_2/pO_2 or pCO_2 only), and whether the pO_2 parameter is set to ON or OFF in Technical setup.

Continued on next page

Normal view, *Continued*

Selecting Normal view options *(continued)*

Step	Action
2.	Use the ***Up*** and ***Down*** arrows to select the time span. **NOTICE:** The time span selection only applies to the pCO_2, pO_2 and Power curves.
3.	Select the curve range options of the individual parameters by pressing each of the parameters and, in the appearing screens, selecting the high and low values.
4.	Press ***OK*** to accept the changes and return to the Normal view setup screen, or press ***Cancel*** to return to the Normal view setup screen without saving changes.
5.	If required, select (✓) the screen saver. **NOTICES:** • To activate the screen saver, it is necessary to press ***OK*** before leaving the Normal view setup. • The option is only visible if it has been activated in Technical settings. • The screen saver is primarily meant for sleep labs, to reduce the backlight from the display. • Touching the screen deactivates the screen saver; and to reactivate it, the option must be selected in Normal view setup.
6.	Press: • ***OK*** to accept the changes and return to the main screen • ***Apply*** to accept the changes without leaving the Normal view setup • ***Cancel*** to return to the main screen without saving changes

Trend table view

Introduction

In the Trend table setup, it is possible to select the time interval between each record in the Trend table.

Accessing the program

To access the Trend table setup, press ***Setup*** → ***Trend table***.

Selecting Trend table options

Step	Action
1.	Use the ***Up*** and ***Down*** arrows to select the time interval.
2.	Press: • ***OK*** to accept the changes and return to the main screen • ***Apply*** to accept the changes without leaving the Trend table setup • ***Cancel*** to return to the main screen without saving changes

Trend curve view

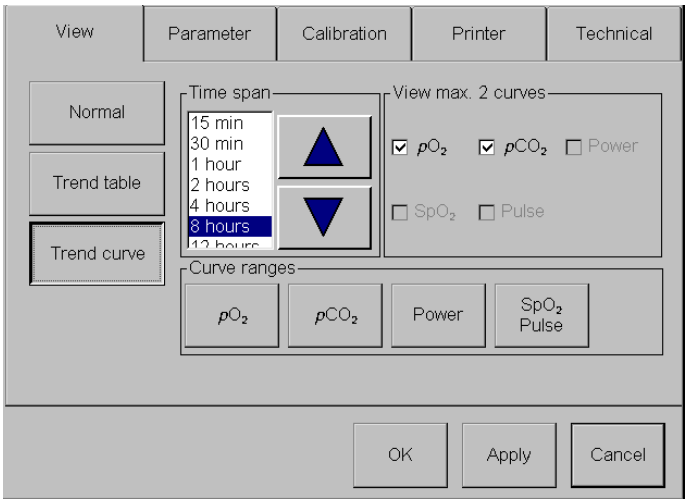
Introduction

In the Trend curve setup, it is possible to set the time span of the graphic display and the ranges for pCO_2, pO_2, Power and SpO_2/Pulse, and to select which parameter(s) (maximum two) should be displayed on the Trend curve.

NOTICE: SpO_2 and pulse are available on the TCM40 monitor only.

Accessing the program

To access the Trend curve setup, press ***Setup*** → ***Trend curve***.



Selecting Trend curve options

Step	Action
1.	Use the ***Up*** and ***Down*** arrows to select the time span.
2.	Select maximum two parameters to be displayed as trend curves. **NOTICE:** If two parameters are selected, one of these must be deselected in order to be able to select a new parameter.
3.	Select the curve range options of the individual parameters by pressing each of the parameters and, in the appearing screens, selecting the high and low values, using the arrow keys.
4.	Press ***OK*** to accept the changes and return to the Trend curve setup screen, or press ***Cancel*** to return to the Trend curve setup screen without saving changes.
5.	In the Trend curve setup screen, press: • ***OK*** to accept the changes and return to the main screen • ***Apply*** to accept the changes without leaving the Trend curve setup • ***Cancel*** to return to the main screen without saving changes

Parameter setup

WARNING – *Risk of incorrect monitoring*
Make sure to select the alarm limits carefully. Setting alarm limits to extreme values can render the alarm system useless.

pCO_2

Accessing the program

To access the pCO_2 setup, press ***Setup*** → ***Parameter*** → ***p*CO₂**.

pCO_2 settings

Settings	Options
pCO_2 alarm	ON/OFF **NOTICE:** The alarm is triggered if the parameter value exceeds or is equal to the alarm limit (high or low). It consists of a visual part (the parameter value and an alarm text will be flashing) and an acoustic part (a discontinuous tone).
pCO_2 alarm high	6-200 mmHg (in steps of 1); 0.8-26.7 kPa (in steps of 0.1)
pCO_2 alarm low	5-99 mmHg (in steps of 1); 0.7-9.9 kPa (in steps of 0.1)
Alarm sound level[1]	1-5 (1 is minimum)
Sensor temp. [2]	37.0-45.0 °C (in steps of 0.5) **NOTICE:** If the set sensor temperature is changed during measurement, a new calibration is required.
SmartHeat[2]	ON/OFF **NOTICE:** If SmartHeat is set to ON, it adds +1 °C (max. temp. 45 °C) to the set sensor temperature for 5 minutes after the sensor has been removed from the calibration chamber.
Site time[2]	OFF; ½-12 hours (in steps of ½ hour)
Site time heat[2]	ON/OFF **NOTICE:** If Site time heat is set to OFF, the sensor heat is switched off when the site timer reaches zero; if set to ON, the heat continues.

[1] The setting of this option is common to pCO_2, pO_2 and SpO_2.
[2] The setting of this option is common to pCO_2 and pO_2.

Selecting pCO_2 settings

Step	Action
1.	Select the relevant option with the ▼ touch key.
2.	Choose the settings of that option with the ***Up*** or ***Down*** arrow key.
3.	Follow steps 1-2 for the remaining options.
4.	Press: • ***OK*** to accept the changes and return to the main screen • ***Apply*** to accept the changes without leaving the pCO_2 setup • ***Cancel*** to return to the main screen without saving changes

pO_2

Accessing the program

To access the pO_2 setup, press ***Setup*** → ***Parameter*** → ***pO_2***.

pO_2 settings

Settings	Options
pO_2 alarm	ON/OFF **NOTICE:** The alarm is triggered if the parameter value exceeds or is equal to the alarm limit (high or low). It consists of a visual part (the parameter value and an alarm text will be flashing) and an acoustic part (a discontinuous tone).
pO_2 alarm high	1-800 mmHg (in steps of 1); 0.1-99.9 kPa (in steps of 0.1)
pO_2 alarm low	0-99 mmHg (in steps of 1); 0.0-9.9 kPa (in steps of 0.1)
Alarm sound level[1]	1-5 (1 is minimum)
Sensor temp.[2]	37.0-45.0 °C (in steps of 0.5) **NOTICE:** If the set sensor temperature is changed during measurement, a new calibration is required.
SmartHeat[2]	ON/OFF **NOTICE:** If SmartHeat is set to ON, it adds +1 °C (max. temp. 45 °C) to the set sensor temperature for 5 minutes after the sensor has been removed from the calibration chamber.
Site time[2]	OFF; ½-12 hours (in steps of ½ hour)
Site time heat[2]	ON/OFF **NOTICE:** If Site time heat is set to OFF, the sensor heat is switched off when the site timer reaches zero; if set to ON, the heat continues.

[1] The setting of this option is common to pCO_2, pO_2 and SpO_2.
[2] The settings of these options are common to pCO_2 and pO_2.

Selecting pO_2 settings

Step	Action
1.	Select the relevant option with the ▼ touch key.
2.	Choose the settings of that option with the ***Up*** or ***Down*** arrow key.
3.	Follow steps 1-2 for the remaining options.
4.	Press: • ***OK*** to accept the changes and return to the main screen • ***Apply*** to accept the changes without leaving the pO_2 setup • ***Cancel*** to return to the main screen without saving changes

SpO_2/Pulse

Accessing the program

To access the SpO_2/Pulse setup, press ***Setup*** → ***Parameter*** → **SpO_2*/Pulse***.

SpO_2/Pulse settings

Settings	Options
SpO_2 alarm	ON/OFF **NOTICE:** The alarm is triggered if the parameter value exceeds or is equal to the alarm limit (high or low). It consists of a visual part (the parameter value and an alarm text will be flashing) and an acoustic part (a discontinuous tone).
SpO_2 alarm high	OFF/86-100 % (in steps of 1) **WARNING – *Risk of patient injury*** Make sure to select the upper alarm limit for oxygen saturation carefully and in accord with accepted clinical standards. High oxygen levels may predispose a premature infant to develop retinopathy. **NOTICE:** SpO_2 alarm high can be disabled ("HI OFF" will be displayed beneath the alarm symbol) while SpO_2 alarm low is kept active.
SpO_2 alarm low	85-99 % (in steps of 1)
SatSeconds	OFF/10-100 (in steps of 10)
Alarm sound level[1]	1-5 (in steps of 1)
Pulse alarm	ON/OFF
Pulse alarm high	35-240 bpm (in steps of 5)
Pulse alarm low	30-235 bpm (in steps of 5)

[1] The setting of this option is common to pCO_2, pO_2 and SpO_2.

Selecting SpO_2/Pulse settings

Step	Action
1.	Select the relevant option with the ▼ touch key.
2.	Choose the settings of that option with the ***Up*** or ***Down*** arrow key.
3.	Follow steps 1-2 for the remaining options.
4.	Press: • ***OK*** to accept the changes and return to the main screen • ***Apply*** to accept the changes without leaving the SpO_2/Pulse setup • ***Cancel*** to return to the main screen without saving changes

Blood gas

Introduction

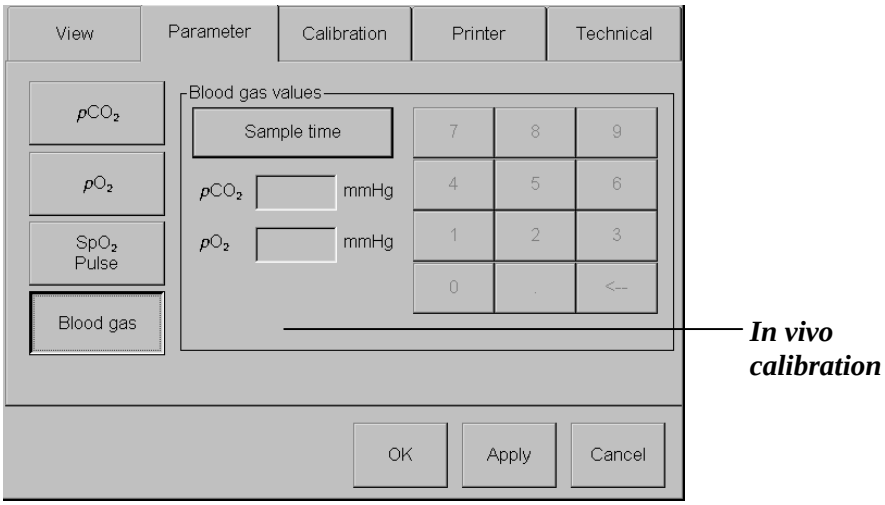
In the Blood gas setup it is possible to:

- key in the blood gas values of a patient to compare these with transcutaneous measurements from the same patient. The blood gas values are displayed as blood drops in all views, as well as on all printed reports.
- calibrate the transcutaneous measurements against the blood gas values (in vivo calibration), and all results will then be displayed as red stars.

Accessing the program

To access the Blood gas setup, press ***Setup*** → ***Parameter*** → ***Blood gas***.

NOTICE: The system must be monitoring.



NOTICE: The ***In vivo calibration*** touch key is only visible if the option has been activated in Technical settings (see *Technical settings* later in this chapter).

Procedures

For the procedures on how to key in a blood gas value and how to perform an in vivo calibration, see *Blood gas comparison* and *In vivo calibration* in chapter 6.

Calibration setup

SmartCal

Purpose

The SmartCal function makes sure that the monitor is always ready for monitoring by calibrating the sensor when needed.

Accessing the program

To access the SmartCal setup, press ***Setup*** → ***Calibration*** → ***SmartCal***.

SmartCal settings

Settings	Options	Function
SmartCal	ON/OFF	Enables/disables the SmartCal function. **NOTICES:** • When enabled, the monitor will calibrate automatically. The calibration interval may vary from 5 minutes to 2 hours; and the maximum measuring time will be reduced accordingly. • Although the option is enabled, it is necessary to press ***Calibrate*** to start a SmartCal period.
SmartCal duration	Forever/ 1-12 hours (in steps of 1)	Defines the duration of the SmartCal period. **NOTICE:** If set to forever, the monitor will calibrate whenever the sensor is placed in the calibration chamber; if set to 1-12 hours, the monitor will calibrate within the selected period, and after a SmartCal period, it will be necessary to press ***Calibrate*** to start a new SmartCal period.
Elapsed time	0:00-12:00 (hours:minutes)	Shows how much time has elapsed of the active SmartCal period.

Selecting SmartCal settings

Step	Action
1.	Select the relevant option with the ▼ touch key.
2.	Choose the settings of that option with the ***Up*** or ***Down*** arrow key.
3.	Follow steps 1-2 for the remaining options.
4.	Press: • ***OK*** to accept the changes and return to the main screen • ***Apply*** to accept the changes without leaving the SmartCal setup • ***Cancel*** to return to the main screen without saving changes

Calibration status

Introduction

The Calibration status screen shows the status of the last calibration.

Accessing the program

To access the Calibration status screen, press ***Setup*** → ***Calibration*** → ***Cal. Status***.

Calibration status information

Status info	Unit	Description
Last cal.	hour:minutes	Shows the time of the last calibration.
Set temp.	°C	Shows the sensor temperature during the last calibration.
Barometer	mmHg/kPa	Shows the barometric pressure during the last calibration.
Cal. value O_2	mmHg/kPa	Shows the O_2 calibration value.
Cal. value CO_2	mmHg/kPa	Shows the CO_2 calibration value.
Gas level	%	Shows how much calibration gas is left in the cylinder. **NOTICE:** The level will be displayed as "High" until there is less than 10 % left in the gas cylinder, and then as a percentage.

Press ***OK*** or ***Cancel*** to return to the main screen.

Printer setup

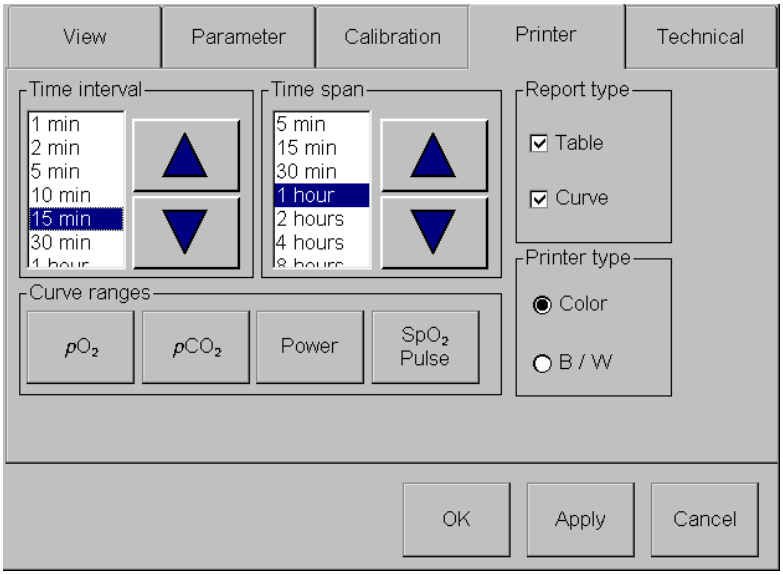
Introduction

In the Printer setup, it is possible to:

- set the time interval between two values on the table printout
- set the time span of the measurements that are to be shown on the printout
- choose whether to print out the report as a table, a curve or both
- adjust the set curve ranges
- connect a color or a black-and-white (B/W) printer to the monitor

Accessing the program

To access the Printer setup, press ***Setup*** → ***Printer***.



NOTICE: SpO_2 and pulse are available on the TCM40 monitor only.

Selecting printer settings

Step	Action
1.	Select the time interval with the ***Up*** and ***Down*** arrow keys.
2.	Select the time span with the ***Up*** and ***Down*** arrow keys. **NOTICE:** The selected time span will influence the start time of the Printer start/stop time screen, as the interval between the printer start time and the printer stop time corresponds to the time span; i.e. if the time span is set to 1 hour, the interval between the printer start time and the printer stop time will also be 1 hour (see also *How to print* in chapter 6: *In vivo monitoring*).
3.	To change the curve range for pCO_2, pO_2, Power or SpO_2/Pulse, press the relevant parameter touch key and select the high and low values, using the ***Up*** and ***Down*** arrows.

Continued on next page

Printer setup, *Continued*

Selecting printer settings *(continued)*	Step	Action
	4.	Press ***OK*** to accept the changes and return to the Printer setup, or press ***Cancel*** to return to the Printer setup without saving the changes.
	5.	Select at least one report type: Table and/or Curve.
	6.	Select printer type: color or B/W (i.e. black and white). **NOTICES:** • It is only possible to connect a local printer to the monitor. Printing over the network is not supported. • Radiometer recommends that you use an HP printer with PCL3 protocol.
	7.	Press: • ***OK*** to accept the changes and return to the main screen • ***Apply*** to accept the changes without leaving the Printer setup • ***Cancel*** to return to the main screen without saving changes

Technical setup

Technical settings

Accessing the program

To access the Technical settings, press ***Setup*** → ***Technical*** *(enter password and press* ***Enter)*** → ***Tech. Settings***.

Technical settings

Settings	Options	Function
Meta. corr. factor	0-15 mmHg (in steps of 1 mmHg); 0-1 kPa (in steps of 0.1 kPa)	Defines the metabolic correction factor. To indicate that CO_2 values have been corrected, "Corr." is displayed together with the pCO_2 value in Normal view.
Severinghaus corr.	ON/OFF	If set to ON, all CO_2 values are corrected with the Severinghaus correction factor, and "Corr." is displayed together with the pCO_2 value in Normal view.
In vivo calibration	ON/OFF	Enables/disables access to the ***In vivo calibration*** touch key in the Blood gas setup.
Cal. gas mix pO_2	0.0-100.0 % (in steps of 0.1)	A calibration constant.
Cal. gas mix pCO_2	0.0-10.0 % (in steps of 0.1)	A calibration constant.
Unit pCO_2/pO_2	mmHg/kPa	Defines the pCO_2/pO_2 unit.
pO_2 parameter	ON/OFF	Defines whether to display the pO_2 parameter or not. **NOTICE:** This option only has an effect when a combined tcpCO_2/tcpO_2 sensor is connected to the monitor.
Alarm mode	Latching/ non-latching	Defines whether the alarm is latching (the monitor remains in alarm status even though the alarm condition ceases to exist) or non-latching (the monitor resets itself as soon as the alarm condition ceases to exist).
Continuous data output	OFF, Standard, VueLink, MonLink or Raw data	Gives four possibilities for data output: standard, VueLink, MonLink and raw data. See chapter 6 for detailed information. **NOTICE:** Raw data is for service purposes only. For more information, see the *TCM4 Series service manual*.

Continued on next page

Technical settings, *Continued*

Technical settings *(continued)*

Option	Range (default)	Function
Data export	OFF, USB or Serial	Enables access to the ***Export*** touch key (in Patient DMS), which is used to export a dump of the trend data to a memory stick or an external PC. **NOTICE:** "Serial" is only available if "Continuous data output" is set to OFF.
Data export interval	2, 10, 30 or 60 seconds	Defines the interval between the export of data.
Display brightness	10-100 % (in steps of 10)	Defines the backlight brightness of the display. **NOTICE:** Full backlight reduces the lifetime of the display.
Screen saver	ON/OFF	Makes a screen saver option available in Normal view setup.
pO_2 analog range	0-200 or 0-800 mmHg; 0.0-26.7 or 0.0-99.9 kPa	Defines the pO_2 analog output range.
pCO_2 analog range	0-100 or 0-200 mmHg; 0.0-13.3 or 0.0-26.7 kPa	Defines the pCO_2 analog output range.

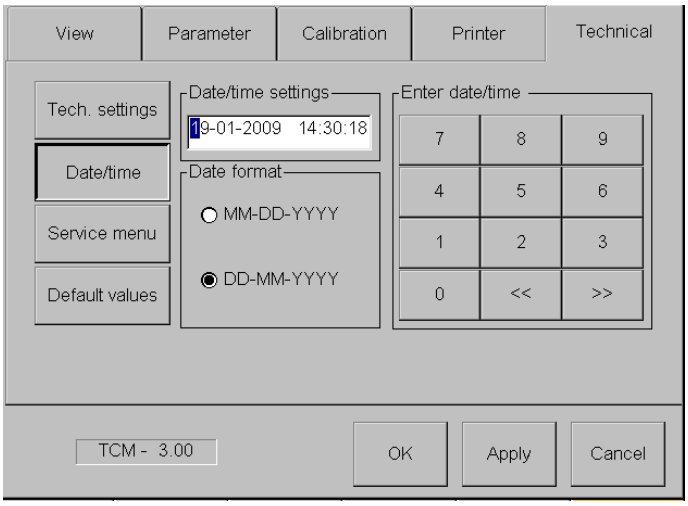
Selecting technical settings

Step	Action
1.	Select the relevant option with the ▼ touch key.
2.	Choose the settings of that option with the ***Up*** or ***Down*** arrow key.
3.	Follow steps 1-2 for the remaining options.
4.	Press: • ***OK*** to accept the changes and return to the main screen • ***Apply*** to accept the changes without leaving the Technical settings • ***Cancel*** to return to the main screen without saving changes

Date/time

Accessing the program

To access the Date/time settings, press ***Setup*** → ***Technical*** *(enter password and press* ***Enter)*** → ***Date/time***.



WARNING – *Risk of data loss*
If the Date/time settings are changed backward in time, only the measurements that have been performed *prior* to the new date/time will be kept in the memory. Other data will be deleted.

.

NOTICE: Date and time cannot be set during measurement. Trying to do so will result in an alert.

Changing date/time settings

The "Date/time settings" input field reflects the current settings.

Step	Action
1.	Select date format: • MM-DD-YYYY (month-day-year) • DD-MM-YYYY (day-month-year)
2.	Move one character at a time in the "Date/time settings" input field with the << and >> touch keys. Enter the new settings with the numeric keypad.
3.	Press: • ***OK*** to accept the changes and return to the main screen • ***Apply*** to accept the changes without leaving the Date/time settings • ***Cancel*** to return to the main screen without saving changes

Default values

Introduction

The Default values function changes all parameter and monitor settings to factory defaults. The default values are listed below.

NOTICE: When changing all settings to factory defaults, all kPa settings will change to mmHg.

Changing settings to factory defaults

Step	Action
1.	Press ***Setup*** → ***Technical*** *(enter password and press* ***Enter****)* → ***Default values***.
2.	A dialog box with the text "This will return the monitor into default setup and current setup will be lost" appears. Press ***OK*** to change all parameter and monitor settings to factory defaults or ***Cancel*** to exit without changing settings.

List of default settings

Menus	Settings	Default
Normal view	Curve selection	TCM40 monitor: pCO_2/pO_2/SpO_2
		TCM4 monitor: pCO_2/pO_2/Power
	Time span	1 hour
Table view	Time interval	15 minutes
Curve view	Time span	8 hours
	Curve selection	TCM40 monitor: pCO_2 and SpO_2
		TCM4 monitor: pCO_2 and pO_2
Curve range	pCO_2 high	60 mmHg/8.0 kPa
	pCO_2 low	0 mmHg/0.0 kPa
	pO_2 high	200 mmHg/26.7 kPa
	pO_2 low	0 mmHg/0.0 kPa
	Power high	400 mW
	Power low	0 mW
	SpO_2 high	100 %
	SpO_2 low	90 %
	Pulse high	200 bpm
	Pulse low	0 bpm

Continued on next page

Default values, *Continued*

List of default settings *(continued)*

Menus	Settings	Default
pCO_2	pCO_2 alarm	ON
	pCO_2 alarm high	50 mmHg/6.7 kPa
	pCO_2 alarm low	30 mmHg/4.0 kPa
	Alarm sound level	2
	Sensor temp.	43.0 °C
	SmartHeat	OFF
	Site time	4 hours
	Site time heat	OFF
pO_2	pO_2 alarm	ON
	pO_2 alarm high	95 mmHg/12.7 kPa
	pO_2 alarm low	60 mmHg/8.0 kPa
	Alarm sound level	2
	Sensor temp.	43.0 °C
	SmartHeat	OFF
	Site time	4 hours
	Site time heat	OFF
SpO_2/Pulse	SpO_2 alarm	ON
	SpO_2 alarm high	OFF
	SpO_2 alarm low	85 %
	SatSeconds	OFF
	Alarm sound level	2
	Pulse alarm	ON
	Pulse alarm high	170 bpm
	Pulse alarm low	40 bpm
Calibration	SmartCal	OFF
	SmartCal duration	4 hours

Continued on next page

Default values, *Continued*

List of default settings *(continued)*

Menus	Settings	Default
Printer	Time interval	15 minutes
	Time span	1 hour
	Report type	Table and curve
	Printer type	Color
Technical	Meta. corr. factor	7 mmHg/1.0 kPa
	Severinghaus corr.	ON
	In vivo calibration	OFF
	Cal. gas mix pO_2	20.9 %
	Cal. gas mix pCO_2	7.5 %
	Unit pCO_2/ pO_2	mmHg
	pO_2 parameter	ON
	Alarm mode	Non-latching
	Continuous data output	OFF
	Data export	OFF
	Data export interval	10 seconds
	Display brightness	70 %
	Screen saver	OFF
	pCO_2 analog range	0-200 mmHg/0.0-26.7 kPa
	pO_2 analog range	0-800 mmHg/0.0-99.9 kPa
Date/time	Date format	DD-MM-YYYY

4. Installation and maintenance

Operating requirements

WARNING – *Risk of incorrect measurements*
Do not use the monitor adjacent to or stacked with other equipment as these can cause electromagnetic interference and thereby result in incorrect measurements. If stacking or use adjacent to other equipment is necessary, the monitor should be observed to verify normal operation before used on patients. See the section *EMC approvals and compliance* in chapter 8.

WARNING – *Risk of incorrect measurements*
When installing, operating or servicing the monitor, special consideration should be given to the information regarding the electromagnetic precautions for this equipment given in the section *EMC approvals and compliance* in chapter 8. Otherwise the monitor may be affected by electromagnetic interference, causing incorrect measurements.

WARNING – *Risk of fire*
Do not place the monitor in an enriched oxygen atmosphere or inside a hyperbaric chamber as it may cause a fire hazard.

WARNING – *Risk of explosion*
Do not use the monitor in the presence of flammable anesthetics or gases as it may cause an explosion.

WARNING – *Risk of fire*
Do not cover the ventilator as this may cause it to seize up.

WARNING – *Risk of electrical shock*
Do not use the monitor if it is damaged as this may result in electrical shock.

Environmental requirements

The following environmental requirements must be observed at all times:

- ambient temperature: 5-40 °C
- relative humidity: 20-80 %.

NOTICE: Do not operate the monitor at ambient temperatures below 5 °C or above 40 °C and relative humidity below 20 % or above 80 %. Operating the monitor outside these limits may affect the readings of the device.

Ventilation requirements

The monitor must be located in a well-ventilated dust-free atmosphere.

Installing the monitoring system

Procedure

Step	Action
1.	**NOTICE:** While installing the modules, the monitor must be turned off. Install the relevant module(s) (i.e. tc and SpO_2) by pressing each module completely into the base unit until a click is heard. **NOTICE:** If using an E5480 sensor, the gasket in the calibration chamber must be code no. 837-488; and if using an E5280 or E5260 sensor, the gasket in the calibration chamber must be code no. 837-159 (see package insert for instructions).
2.	For TCM40 monitor only: Plug the SpO_2 sensor into the monitor. **NOTICE:** It is not necessary for the monitor to be turned off while the sensor is being connected.
3.	Install the calibration gas cylinder and the battery according to the procedures described later in this chapter under *Maintenance of the monitor*.
4.	Connect the monitor power cord to • the power socket at the rear of the monitor and • an appropriate power supply
5.	Connect the system to external equipment, if required. **WARNING – *Risk of personal injury*** Before connecting other equipment to the TCM monitor, the manufacturer of the equipment or a qualified engineer must be consulted to ensure that the equipment is compatible and that the safety of the patient, the operator or the environment will not be impaired. The resulting combined system must comply with EN 60601-1-1.
6.	Turn on the monitor by pressing the power switch to the ON position at the rear of the monitor and then pressing the ON/OFF button on the front of the monitor. **NOTICE:** Every time the monitor is turned on, a beep sounds, indicating that it has been checked that the sound of the alarm system is working. If the sound is not working, an error message is shown.
7.	Check that the date and time in the display correspond with the actual date and time. Otherwise correct them in Technical setup.
8.	Membrane the tc*p*CO_2/tc*p*O_2 sensor as described later in this chapter.
9.	Connect the tc*p*CO_2/tc*p*O_2 sensor plug to the sensor socket at the rear of the tc module, and place the sensor in the calibration chamber at the front.

Continued on next page

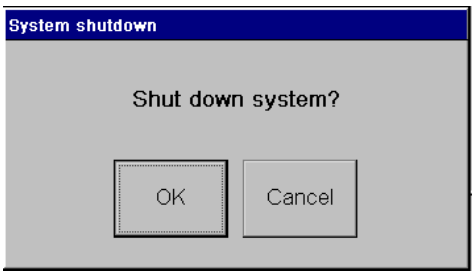
Installing the monitoring system, *Continued*

Procedure ***(continued)***

Step	Action
10.	Check that the tc module is functioning: The message "Calibration required" is displayed on the screen. Leave it until step 12.
11.	Change View or Setup settings, if required, by pressing ***Setup***. See chapter 3: *Menu structure and setup programs*.
	NOTICE: The monitor is delivered with default settings (see these in the section *Default values* in chapter 3).
12.	Calibrate the sensor as described in chapter 5: *Calibration.*

Shutting down the monitor

Shutting down the monitor

Step	Action
1.	Press the ⏻ button on the front of the monitor. The following system message will be displayed: 
2.	Press ***OK*** to shut down the monitor – the message "Saving data. Please wait." will be displayed – or ***Cancel*** to return to the main screen without shutting down the monitor.

Cleaning the monitor

Cleaning the exterior

When cleaning the monitor:

- Shut down the monitor by following the procedure described earlier in this chapter
- Use a cloth that is lightly dampened with soapy water
- Do not use abrasive cleansers or pads: the finish may become damaged
- Do not use aggressive detergents. Extensive use may cause the plastic to become brittle and cracks may occur.

Cleaning the touch screen

A dry or lightly dampened soft, lint-free cloth may be used to clean the monitor's touch screen. Simply wipe the screen gently to remove fingerprints and/or dirt. To avoid streaking, an approved screen cleaner is recommended.

Disinfection of outer surfaces

Disinfection of the monitor exterior and touch screen is performed when appropriate. The disinfection frequency depends on local requirements and the use of the monitor.

NOTICE: Follow legal requirements and local rules for safe work practices with chemicals.

The following disinfectants, dissolved in water, may be used to disinfect the monitor exterior and touch screen:

- 70 % isopropyl alcohol
- 70 % ethanol
- 4 % Diversol BX solution

To disinfect the monitor exterior and touch screen, wipe the surfaces using one of the above disinfectants on a paper towel or tissue.

NOTICE

Do not spray, pour or spill any liquid on the monitor or any of the accessories, connectors, switches or openings in the chassis.

Maintenance of the monitor

Battery

The following battery type must be installed on the monitor: Standard 12 V 2 Ah lead-acid battery (code no. 431-018, available from Radiometer)

Contact your local battery supplier for available type.

CAUTION – *Risk of patient not being monitored*
For data safety reasons, a battery must always be connected to the system.

CAUTION – *Risk of patient not being monitored*
Replace battery only with the types recommended by Radiometer.

CAUTION – *Handling of biohazardous waste*
Dispose of the battery according to local procedures to avoid personal injury or pollution of the environment.

The monitor can function for approx. one hour on battery supply (depending on battery type). When the monitors run on battery, it is indicated on the display, and the battery level indicator shows the battery level. If the battery level is low, an alert sound is heard and the battery level indicator is flashing. If the battery level is critically low, an alert message will furthermore be displayed.

CAUTION – *Risk of patient not being monitored*
Make sure the battery level never becomes critically low, as this will prevent data from being saved onto the disk.

To avoid a complete discharge of the battery, reconnect the monitor to the mains as soon as possible to recharge the battery. Recharging the battery takes approximately 8 hours.

Changing the battery

Step	Action
1.	Unscrew the battery cover at the rear of the monitor.
2.	Detach the battery from the connector.
3.	Attach a new battery to the connector.
4.	Reattach the battery cover.

Continued on next page

Maintenance of the monitor, *Continued*

Changing the calibration gas

Step	Action
1.	Unscrew the old calibration gas cylinder.
	WARNING – *Risk of explosion* Calibration gas cylinder: Contents under pressure. Do not puncture. Do not use or store near heat or open flame. Exposure to temperatures above 54 °C (for CAL2) and 50 °C (for CAL1) may cause contents to vent or cause bursting. Never discard container into fire or incinerator as it may cause an explosion.
2.	Screw the new calibration gas cylinder clockwise as far as possible into the socket.
	NOTICE: Excessive force may damage threads and result in a leakage and thereby an increase in consumption.

Changing the gasket in the calibration chamber

Step	Action
1.	Remove the gasket from the calibration chamber.
2.	Clean the calibration chamber with a soft cloth moistened with skin antiseptic, e.g. 70 % alcohol.
3.	Mount a new gasket into the calibration chamber.
	NOTICE: Be sure to align the gasket correctly.

Preparation and maintenance of the tc sensors

General information about membraning

To obtain reliable measurements, remembrane the sensor every week.

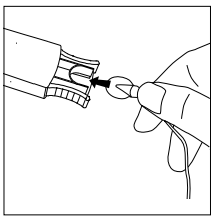
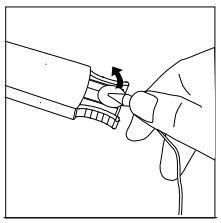
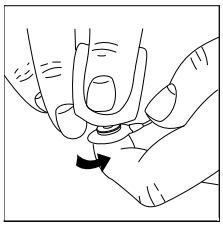
WARNING – *Risk of incorrect measurements (sensor failure)*
After remembraning the sensor, check that the membrane has been clicked completely and centrally onto the sensor housing. Otherwise it may cause the sensor to fail.

When a sensor has been remembraned, connect the sensor plug to the sensor socket at the rear of the monitor. Check that the system shows "Calibration required" and calibrate the sensor twice as described in chapter 5: *Calibration*.

Cleaning the sensor head of the E5480 sensor

Cleaning the sensor head

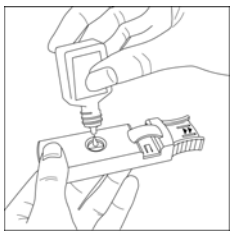
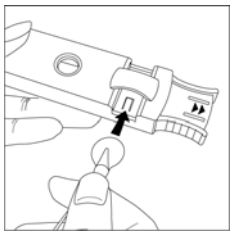
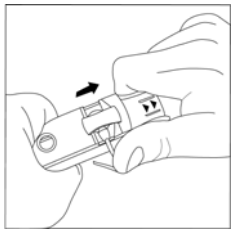
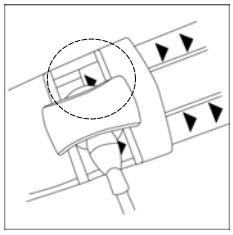
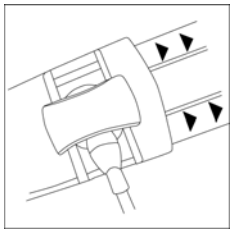
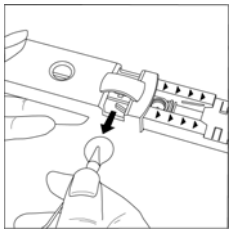
NOTICE: Once a month, the sensor head must be cleaned to remove old electrolyte before the sensor is remembraned.

Step		Action
1.		Slide the sensor into the end of the membraning tool.
2.		Pull the sensor upwards to remove the membrane.
3.		Clean the sensor head with cleaning paper and remembrane the sensor as described on next page.

Membraning the E5480 sensor

Membraning the sensor

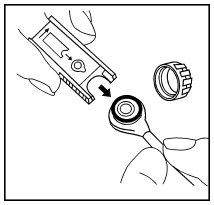
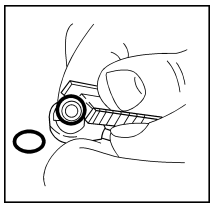
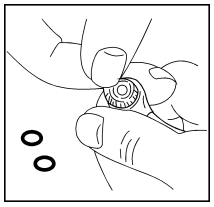
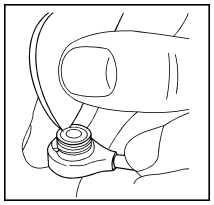
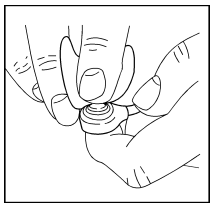
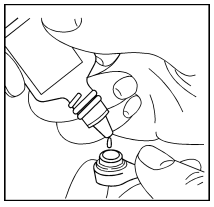
To membrane the sensor, use a membraning kit (code no. 905-805).

Step		Action
1.		Apply two drops of electrolyte solution to the membraning tool. **NOTICE:** Ensure that there are no air bubbles in the electrolyte solution. If air bubbles are present, wait a few seconds and check again.
2.		Place the sensor (without the protection cap) in the sensor slot.
3.		a) To remove the old membrane, grip the membraning tool firmly at both ends.
		b) Pull in the direction of the arrows until only one arrow is visible in the sensor slot.
4.		To click on the new membrane, pull forcefully in the direction of the arrows until the tool locks and no arrows are visible in the sensor slot.
5.		Remove the sensor and wipe off the surplus electrolyte solution with cleaning paper.

Membraning the E5280 and E5260 sensors

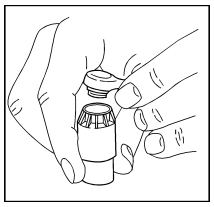
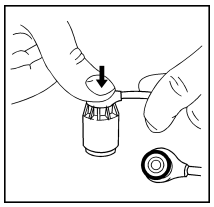
Membraning the sensor

To membrane the sensor, use a membraning kit (code no. 904-892).

Step		Action
1.		Remove the protection cap. Then remove the old O-rings by sliding the O-ring remover under the O-ring, just above the arrow on the sensor house.
2.		Turn the O-ring remover clockwise to release the two O-rings.
3.		Peel off the old membranes.
4.		Clean the sensor surface: Absorb the old electrolyte solution with the cleaning paper.
5.		Rub the sensor measuring surface carefully two or three times to remove the thin layer of silver that has precipitated on the sensor.
6.		Apply two drops of the tcpCO_2/tcpO_2 electrolyte solution on the surface of the sensor. **NOTICE:** Check that the electrolyte solution covers the entire surface without air bubbles.

Continued on next page

Membraning the E5280 and E5260 sensors, *Continued*

Membraning the sensor *(continued)*	Step		Action
	7.		• Place the membrane unit on a hard and stable surface. • Turn the sensor slowly so that the measuring surface faces downwards. • Insert the sensor head into the top of the green membrane unit.
	8.		• Press the sensor firmly into the unit until a click is heard. • Remove the sensor from the unit and wipe off the surplus electrolyte solution with the cleaning paper.

Cleaning, disinfection and storage of sensors

Cleaning the sensors

Wipe the following parts gently with a soft cloth moistened with skin antiseptic, e.g. 70 % alcohol:

- the sensor head
- the cable

NOTICE: Constant use of hand lotion containing isopropanol/propylalcohol and alcohol prior to handling the sensor may damage the cable. To avoid transferring lotion to the cable, dry hands prior to handling the sensor.

Disinfection

WARNING – *Risk of infection*
Due to the nature and seriousness of diseases such as the Human Immunodeficiency Virus (HIV) (the causative agent of AIDS) and Hepatitis B, always regard equipment and accessories that can come into contact with human or animal tissues or fluids (particularly blood) as contaminated and potentially hazardous to avoid the risk of infection.

Disinfection of the sensor is carried out with a membraned sensor and normally prior to calibration.

Disinfection of the sensor and the cable can be carried out by immersing the sensor and the cable in a water-based disinfection solution, such as a germicidal water-based solution (e.g. one based on n-alkyl dimethyl benzyl ammonium chloride with isopropanol).

WARNING – *Risk of incorrect measurements (sensor failure)*
Do not immerse the sensor plug in disinfection solution. Immersing the sensor plug in disinfection solution will cause the sensor to fail.

WARNING – *Risk of incorrect measurements (sensor failure)*
Do not heat sterilize as the sensor cannot tolerate temperatures exceeding 70 °C. Heat sterilization of the sensor will cause it to fail.

As the number of disinfection solutions is increasing and may vary from country to country and from hospital to hospital, it is not possible to come up with a complete list of water-based disinfection solutions that may be used.

However, Radiometer proposes that one of the following water-based disinfection solutions is used:

- MadaCide-FD (MADA Inc.)
- Control III (Maril Products Inc.)
- Hi-Tor Plus (Ecolab Inc.)
- 3.2 % aqueous glutaraldehyde solution (Surgikos - Johnson & Johnson Medical)

Solutions solely based on isopropanol/propylalcohol should be avoided as frequent use of isopropanol/propylalcohol may damage the electrode cable.

NOTICE: To establish the correct disinfection procedure for your hospital, it is important that you consult the hygiene committee at your hospital.

Storage

You may keep the sensors stored in the calibration chambers. For longer periods of storage, keep the sensors mounted with a protective cap.

NOTICE: Add two drops of electrolyte solution to the cap.

Maintenance of the SpO_2 sensors

Cleaning the SpO_2 sensors

The SpO_2 sensors may be surface-cleaned with a solution such as 70 % isopropyl alcohol. If low-level disinfection is required, use a 1:10 bleach solution. Do not use undiluted bleach (5-5.25 % sodium hypochlorite) or any cleaning solution other than those recommended here because permanent damage to the sensor could occur.

WARNING – *Risk of incorrect measurements (sensor failure)*
Do not expose connector pins to cleaning solution as this may damage the SpO_2 sensor.

WARNING – *Risk of incorrect measurements (sensor failure)*
Do not sterilize the SpO_2 sensor by irradiation, steam or ethylene oxide as this may damage the sensor.

There are two recommended cleaning/disinfection methods:

- The wipe method (for all three SpO_2 sensors)
- The soak method (for Oxiband A/N and P/I sensors only)

Wipe method procedure

Step	Action
1.	Saturate a clean, dry gauze pad with the cleaning solution. Wipe all surfaces of the sensor and cable with this gauze pad.
2.	Saturate another clean, dry gauze pad with sterile or distilled water. Wipe all surfaces of the sensor and cable with this gauze pad.
3.	Dry the sensor and cable by wiping all surfaces with a clean, dry gauze pad.

Soak method procedure

For Oxiband A/N and P/I sensors only.

WARNING – *Risk of incorrect measurements (sensor failure)*
Do not immerse or wet the DS100A sensor as this may damage the sensor.

Step	Action
1.	Place the sensor in the cleaning solution, such that the sensor head(s) and desired length of cable are completely immersed. **WARNING – *Risk of incorrect measurements (sensor failure)*** Do not immerse the connector end of an SpO_2 sensor cable as this may damage the sensor.
2.	Dislodge air bubbles by gently shaking the sensor and cable.
3.	Soak the sensor and the cable for 10 minutes.
4.	Remove from cleaning solution.
5.	Place the sensor and the cable in room-temperature sterile or distilled water for 10 minutes.
6.	Remove from the water.
7.	Dry the sensor and cable by wiping all surfaces with a clean, dry gauze pad.

5. Calibration

General information

To ensure accurate and safe performance of the sensor, it must be calibrated according to the recommendations below.

Calibration material

To calibrate the sensor, use the CAL1 standard calibration gas mixture (7.5 % CO_2, 20.9 % O_2, balance N_2).

SmartCal

The SmartCal function makes sure that the monitor is always ready by calibrating when needed for a period of time that is defined by the operator (1-12 hours or forever).

Calibration frequency

SmartCal	Explanation
ON	If SmartCal is ON and the duration is set to forever or 1-12 hours, a calibration will be performed automatically every 4 hours (i.e. whenever the sensor is placed in the calibration chamber and within the selected SmartCal period). **NOTICE:** If the duration is set to 1-12 hours, it will be necessary to press ***Calibrate*** to start a new SmartCal period after the first period ended.
OFF	If SmartCal is OFF, Radiometer recommends performing a manual calibration: • every time the sensor has been remembraned • prior to each monitoring period • when changing measuring sites • every 4 hours **NOTICE:** If the sensor was not in use for an extended time period, it is recommended to select SmartCal ON and to allow at least 4 hours for stabilization of the sensor in the calibration chamber.

Recommendation

Check the barometer of the monitor against a known calibrated barometer periodically. See ranges in chapter 8: *Specifications and ordering information*.

Calibration

Calibrating the sensor manually

If the SmartCal function is OFF, the sensor must be calibrated manually using the procedure below.

WARNING – *Risk of incorrect measurements*
When performing a gas calibration, make sure the calibration gas mixture is set to 7.5 % for pCO_2 and 20.9 % for pO_2 as incorrect calibration values may cause incorrect measurements.

See Technical settings in chapter 3: *Menu structure and setup programs*.

Step	Action
1.	Make sure the sensor is placed in the calibration chamber.
2.	Press ***Calibrate***. A bar appears on the screen, showing the progress of the calibration. Furthermore, the screen contains information on barometric pressure and, if there is 10 % or less gas left in the gas cylinder, a bar will show the gas level. **NOTICES:** • If SmartCal has been activated in the setup, pressing the ***Calibrate*** touch key will start the SmartCal period. • During calibration it is not possible to reactivate the ***Calibrate*** touch key, which will be grayed out.
3.	When the calibration is complete, the Ready screen appears.

NOTICES

- If the sensor has been remembraned or if it has not been used for 24 hours or more, it must be calibrated twice. Either calibrate the sensor, leave it in the calibration chamber for 30 minutes and then calibrate it again; or enable the SmartCal function, press ***Calibrate*** and then leave the sensor in the calibration chamber for 30 minutes.
- If SmartCal is OFF and the sensor is not removed from the calibration chamber within 30 minutes after Ready, the heat to the sensor will be switched off and a new calibration will be required.

Checking zero current and sensitivity

Recommendations

The zero current of pO_2 and the sensitivity of pCO_2 should be checked if the sensor performance appears to deteriorate.

Items required

The following items are required:

- CAL2 standard calibration gas (10 % CO_2 with N_2 as balance)
- Gas adapter for CAL2 gas

Checking pO_2 zero current and pCO_2 sensitivity

Step	Action
1.	Before calibrating the sensor, set the metabolic correction factor to zero and the Severinghaus correction factor to "OFF" in the Technical setup.
2.	Calibrate the sensor.
3.	Attach the adapter to the CAL2 gas cylinder and place the sensor in the calibration chamber of the gas adapter.
4.	The pCO_2 reading is displayed on the screen. It should be within 73-79 mmHg (9.7-10.5 kPa) within 10 minutes after the sensor has been placed in the calibration chamber of the gas adapter.
5.	Read the tcpO_2 value on the screen: • If under 5 mmHg (0.7 kPa), the sensor is in good condition. • If equal to or above 5 mmHg (0.7 kPa), the sensor must be remembraned and recalibrated. Then repeat steps 1-3 of this procedure. **NOTICE:** If the tcpO_2 reading is still equal to or above 5 mmHg (0.7 kPa), the sensor is defective.
6.	After zero current and sensitivity have been checked, unscrew the CAL2 gas cylinder from the gas adapter.
7.	Remember to reset the metabolic correction factor to "7" and the Severinghaus correction factor to "ON" in the Technical setup.

NOTICE: Lack of sensitivity may be due to insufficient removal of used electrolyte solution during the membraning procedure. In such cases, it is recommended to remembrane the sensor according to the procedure described in chapter 4: *Installation and maintenance.*

6. Patient monitoring

General information

Measuring sites

tc*p*CO_2/tc*p*O_2 measurements:

Clinical studies have shown the abdomen and chest to be the best measuring sites for both neonates and adults.

Saturation measurements:

- Nellcor Durasensor DS100A sensor:
  - Patient (> 40 kg): The preferred site is the index finger, or alternatively a smaller finger, but *not* the thumb.
- Nellcor Oxiband A/N sensor:
  - Adult (> 40 kg): The preferred site is around an index finger, with the cable positioned along the top of the finger. Alternatively, use a thumb or another finger, with the cable positioned along the palm; or around a great toe, with the cable positioned along the sole of the foot.
  - Neonate (< 3 kg): The preferred site is the foot, below the toes, with the cable positioned along the sole of the foot. Alternatively, place the sensor around the palm of a hand, below the fingers, with the cable positioned along the palm.
- Nellcor Oxiband P/I sensor:
  - Pediatric (15-40 kg): The preferred site is around an index finger, with the cable positioned along the top of the finger. Alternative sites are around the thumb or another finger, with the cable positioned along the top of the finger; or a great toe, with the cable positioned along the sole of the foot.
  - Infant (3-15 kg): The preferred site is around a great toe, with the cable positioned along the sole of the foot.

NOTICE: The monitor must only be connected to sensors for one patient at a time.

tc*p*CO_2/tc*p*O_2 sensor temperature

For neonates, a sensor temperature between 42 and 44 °C is recommended.

For adults, a sensor temperature between 43 and 45 °C is recommended.

WARNING – *Risk of burns*
Do not allow the tc*p*CO_2/tc*p*O_2 sensor temperature to exceed 43 °C for neonates and 44 °C for adults if sensors are attached to skin for more than four hours as this may otherwise cause burns.

General alerts

WARNING – *Risk of incorrect measurements*
Do not use the sensors during MRI scanning. Conducted current may cause burns. Also, the sensors may affect the MRI image, and the MRI unit may affect the accuracy of oximetry measurements.

WARNING – *Risk of strangulation*
As with all medical equipment, carefully route and affix patient cabling using the cable clip to reduce the possibility of patient entanglement or strangulation.

WARNING – *Risk of skin damage*
To avoid the risk of skin damage, make sure to set SmartHeat to OFF before applying the sensor to a neonate.

Continued on next page

General information, *Continued*

General alerts *(continued)*

WARNING – *Risk of incorrect measurements*
Remove the sensors from the patient immediately if the system or patient is exposed to a defibrillator, electrocautery or other high-frequency electrical signals, as these may affect the device and may cause injury to the patient.

WARNING – *Risk of fire*
Do not place the monitor in an enriched oxygen atmosphere or inside a hyperbaric chamber as it may cause a fire hazard.

WARNING – *Risk of personal injury*
Make sure to select the upper alarm limit for oxygen saturation carefully and in accord with accepted clinical standards. High oxygen levels may predispose a premature infant to develop retinopathy.

WARNING – *Risk of skin damage*
Long-term hyperthermia may blister skin. When producing local hyperemia by means of hyperthermia, a certain risk of applying temperatures harmful to the skin is always present, although the risk is limited due to the control system of the instrument. Always pay attention to the use of hyperthermia for special patients – e.g. patients in shock, patients with low blood pressure, and patients with vascular constrictions.

WARNING – *Risk of bruises*
When applying a fixation ring to a patient, make sure to place it so that the patient does not lie on top of it, as this may cause the fixation ring to leave bruises on the patient.

WARNING – *Risk of incorrect measurements*
Always keep protection caps on the tc*p*CO_2/tc*p*O_2 sensors (except when applied to skin, placed in the calibration chamber or during handling and maintenance). Exposing sensor membranes to light (for example light from incubators) may cause elevated *p*CO_2 values.

WARNING – *Risk of incorrect measurements*
Do not use the monitor adjacent to or stacked with other equipment as these can cause electromagnetic interference and thereby result in incorrect measurements. If stacking or use adjacent to other equipment is necessary, the monitor should be observed to verify normal operation before used on patients. See the section *EMC approvals and compliance* in chapter 8.

WARNING – *Risk of incorrect measurements*
When installing, operating or servicing the monitor, special consideration should be given to the information regarding the electromagnetic precautions for this equipment given in the section *EMC approvals and compliance* in chapter 8. Otherwise the monitor may be affected by electromagnetic interference, causing incorrect measurements.

WARNING – *Risk of incorrect measurements*
The use of sensors, cables and accessories other than those specified may result in increased emission and/or decreased immunity and inaccurate readings of the monitor.

Continued on next page

General information, *Continued*

General alerts *(continued)*

WARNING – *Risk of incorrect measurements*
tc*p*CO_2/tc*p*O_2 monitoring should not be used on patients in a compromised hemodynamic state as this may cause incorrect measurements.

WARNING – *Risk of incorrect measurements*
Using the SpO_2 sensors in the presence of high ambient light may result in inaccurate measurements. In such cases, cover the sensor site with an opaque material.

WARNING – *Risk of incorrect measurements*
Remove any intravascular dyes or externally applied coloring such as nail polish, dye or pigmented cream as they may lead to inaccurate pulse oximetry measurements.

WARNING – *Risk of incorrect measurements*
Pulse oximetry readings and pulse signal can be affected by certain ambient environmental conditions, sensor application errors and certain patient conditions. See the appropriate sections of the manual for specific safety information.

WARNING – *Risk of incorrect measurements*
Always select the measuring site carefully to avoid selecting a site with low perfusion or low signal quality, which can cause incorrect measurements.

WARNING – *Risk of patient not being monitored*
Do not use a NIBP cuff or other constricting devices on the same appendage as the sensor. A NIBP cuff will interrupt the patient's circulatory blood flow and result in no pulse found or loss of pulse.

TCM40 performance considerations

Certain patient conditions can affect the measurements of the monitor and cause the loss of the pulse signal.

Inaccurate measurements can be caused by:

- prolonged patient movement
- venous pulsations
- intravascular dyes, such as indocyanine green or methylene blue
- defibrillation

Dysfunctional hemoglobins such as carboxyhemoglobin, methemoglobin, and sulfhemoglobin are unable to carry oxygen. SpO_2 readings may appear normal; however, a patient may be hypoxic because less hemoglobin is available to carry oxygen. Further assessment beyond pulse oximetry is recommended.

Anemia causes decreased arterial oxygen content. Although SpO_2 readings may appear normal, an anemic patient may be hypoxic. Correcting anemia can improve arterial oxygen content. The monitor may fail to provide an SpO_2 if hemoglobin levels fall below 5 g/dL.

Saturation: The monitor displays saturation levels between 1 and 100 %.

Pulse rates: The monitor displays pulse rates between 20 and 300 beats per minute. Detected pulse rates outside the range of 20 to 300 beats per minute are displayed as the closest value within the range.

Continued on next page

General information, *Continued*

SpO_2 sensor performance considerations

Inaccurate measurements may be caused by:

- incorrect application of the sensor
- placement of the sensor on an extremity with a blood pressure cuff, arterial catheter, or intravascular line
- ambient light
- prolonged patient movement

Loss-of-pulse signal can occur for the following reasons:

- The sensor is applied too tightly
- A blood pressure cuff is inflated on the same extremity as the one with the sensor attached
- There is arterial occlusion proximal to the sensor

Use only Radiometer-recommended sensors and sensor cables.

Select an appropriate sensor, apply it as directed and observe all warnings and cautions presented in the directions for use accompanying the sensor. Clean and remove any substances such as nail polish from the application site. Periodically check to ensure that the sensor remains properly positioned on the patient.

WARNING – *Risk of skin damage*
Inspect the sensor site as directed in the sensor directions for use. Incorrect application or inappropriate duration of use of an SpO_2 sensor can cause skin damage.

WARNING – *Risk of incorrect measurements*
Make sure the sensor is applied correctly. Incorrect application of the SpO_2 sensor can cause incorrect measurements.

High ambient light sources such as surgical lights (especially those with a xenon light source), bilirubin lamps, fluorescent lights, infrared heating lamps, and direct sunlight can interfere with the performance of an SpO_2 sensor. To prevent interference from ambient light, ensure that the sensor is properly applied and cover the sensor site with opaque material.

If patient movement presents a problem, try one or more of the following remedies to correct the problem:

- Verify that the sensor is properly and securely applied
- Move the sensor to a less active site
- Use an adhesive sensor that tolerates some patient motion
- Use a new sensor with fresh adhesive backing

Application and removal of tc sensors

Required materials for application of sensors

The following items, included in the fixation kits, are required to apply the tc sensors to a patient:

- Fixation ring

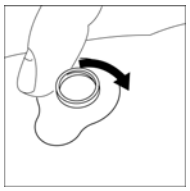
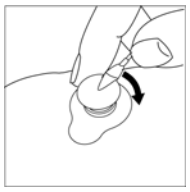
  WARNING – *Risk of infection and inaccurate results*
  Reuse of single-use devices may lead to infection of patients and inaccurate results.

- Contact liquid

Prior to sensor application

Step	Action
1.	Calibrate the sensor as described in chapter 5: *Calibration*.
2.	Clean the selected measuring site with alcohol or other skin-preparation solution.
3.	Dry the site well with a gauze pad.

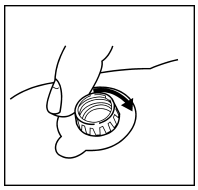
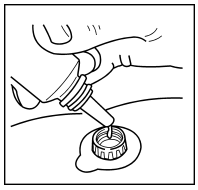
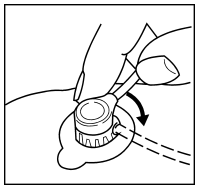
Application of E5480 sensor

Step		Action
1.		Take a fixation ring and remove the protective film.
2.		Apply the fixation ring to clean and dry skin by pressing the center of the fixation ring onto the measuring site with a finger and then running a finger around the rim circumference to ensure a good seal.
3.		Apply 2 drops of contact liquid in the center of the ring.
4.		Place the sensor (without the protection cap) in the fixation ring with the sensor cord pointing in the opposite direction of the tab on the ring. Then turn the sensor a quarter of a turn clockwise to fasten it in the fixation ring.

Continued on next page

Application and removal of tc sensors, *Continued*

Application of E5280 and E5260 sensors

Step		Action
1.		Take a fixation ring and remove the protective film.
2.		Apply the fixation ring to the measuring site by pressing the center of the fixation ring onto the measuring site with a finger and then running a finger around the rim circumference. **NOTICE:** Press firmly to prevent leaks.
3.		Fill the center of the fixation ring with 3-5 drops of the contact liquid.
4.		Remove the sensor from the calibration chamber, align the arrow on the sensor with one of the marks on the fixation ring and turn the sensor a quarter of a turn clockwise to fasten it in the fixation ring.

Removal of sensor

Step	Action
1.	Remove the sensor from the fixation ring by turning it anticlockwise.
2.	Remove the fixation ring by lifting the tab.
3.	Clean the sensor surface carefully with an alcohol swab.
4.	Then place the sensor in the calibration chamber.

Application of SpO_2 sensors

Required materials for SpO_2 monitoring

Saturation monitoring is only available on the TCM40 monitor.

The following items are required to apply an SpO_2 sensor to a patient:

- Nellcor SpO_2 sensor
- Adhesive wrap model ADH-A/N or FOAM-A/N (for Oxiband A/N and Oxiband P/I sensors)
- Nellcor DOC-10 pulse oximetry cable

WARNING – *Risk of incorrect measurements*
Use only Nellcor oximetry brand SpO_2 sensors and sensor cables. And before use, carefully read the sensor directions for use, including all warnings, cautions and instructions. Incorrect use can cause incorrect measurements.

WARNING – *Risk of incorrect measurements*
Use only the DOC-10 pulse oximetry cable and do not increase the length of the sensor by connecting an extra sensor cable. Use of another sensor cable or more than one cable will have an adverse effect on performance.

WARNING – *Risk of skin damage*
Use only Nellcor oximetry brand wraps designed for use with the SpO_2 sensor. Do not use tape. Use of additional tape or various other types of wraps can cause skin damage.

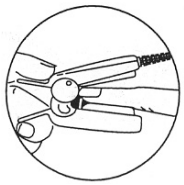
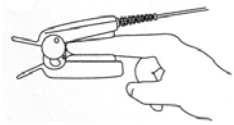
NOTICES:

- Radiometer provides a starter kit containing sensor (Nellcor DS100A, Nellcor Oxiband A/N or Nellcor Oxiband P/I), wraps and cable. New sensors (or other Nellcor sensors than the one in the starter kit), wraps and cables must be ordered from your local Nellcor agent.
- When selecting an SpO_2 sensor, consider the patient's weight and activity level, the adequacy of perfusion and the available sensor sites, the need for sterility and the anticipated duration of monitoring.
- When selecting a sensor site, priority should be given to an extremity free of an arterial catheter, blood pressure cuff or intravascular infusion line.
- Before applying the sensor, clean and remove any substances, such as nail polish, from the application site.

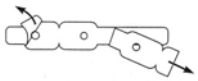
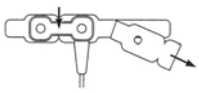
Continued on next page

Application of SpO_2 sensors, *Continued*

Application of DS100A sensor

Step		Action
1.		Place the patient's index finger over the sensor window of the DS100A sensor with the fingertip against the stop.
2.		If the fingernail is long, the nail tip will extend over the finger stop.
3.		Spread open the rear tabs of the sensor to provide even force over the length of the pads. Check the position of the sensor. If an index finger cannot be positioned correctly, or is not available, a smaller finger can be used, or use another sensor. **NOTICE:** Do not use the DS100A on a thumb or toe or across a child's hand or foot.
4.		The sensor should be oriented in such a way that the cable is positioned along the top of the hand.

Application of Oxiband A/N and P/I sensors

Step		Action
1.		Place the wrap on a flat surface, adhesive (sticky) side up, with the tab on the left.
2.		Remove the small piece of paper backing and enough of the large piece of backing to expose both alignment holes.
3.		Position the sensor on the wrap so the alignment bumps protrude through the holes. Press down firmly in the center of the sensor to ensure that the wrap adheres tightly.
4.		Remove the remainder of the paper backing from the wrap. The sensor and wrap are now ready to be applied to the patient. Select an appropriate site as described previously in this chapter under *General information*.

Continued on next page

Application of SpO_2 sensors, *Continued*

Application of Oxiband A/N and P/I sensors *(continued)*

Step	Action
5.	Position the sensor so that the notches are centered on the side of the measuring site. The cable end must be positioned along the appropriate surface, as described previously in this chapter under *General information*.
6.	Wrap the sensor around the measuring site so the optical components (and alignment bumps) oppose each other across the site. Press the sensor to ensure that it adheres snugly.
7.	Wrap the remaining portion of the sensor wrap around the site, loosely enough to ensure good circulation.

Removal of wraps

The disposable wraps used with the Oxiband A/N and P/I sensors should be removed by peeling them away from the sensor.

WARNING – *Risk of sensor damage*
Do not use excessive force when removing the disposable wrap from the sensor, as it may damage the sensor.

Patient monitoring (In vivo monitoring)

Patient monitoring

Step	Action
1.	Apply the sensor(s) as described earlier in this chapter and wait for a stable reading. **NOTICES:** • The physiological stabilization time of a patient is 10-20 minutes for the tc*p*O_2 reading. Longer time may indicate incorrect sensor application or a poorly selected measuring site. • The physiological stabilization time of a patient is 5-10 minutes for the tc*p*CO_2 reading. Longer time may indicate incorrect sensor application or a poorly selected measuring site. • Excessive motion may compromise performance. In such cases, try to keep the patient still or change the sensor site to one with less motion. • If SmartHeat is set to ON, it adds +1 °C (max. temp. 45 °C) to the set sensor temperature for 5 minutes after the sensor has been removed from the calibration chamber. • If the SpO_2 sensor does not track the pulse reliably, it may be incorrectly positioned or the sensor site may be too thick, thin or deeply pigmented, or otherwise deeply colored (for example as a result of externally applied coloring such as nail polish, dye or pigmented cream) to permit appropriate light transmission. If any of these situations occurs, reposition the sensor or choose an alternate sensor for use on a different site. • The visual indication of the plethysmograph curve is not proportional to the pulse volume.
2.	Press ***Site time*** to reset the site timer to the value selected in Parameter setup, if required. The site timer applies to tc*p*CO_2/tc*p*O_2 only. **NOTICES:** • The site timer will count down to zero at 1-minute intervals, and when it reaches zero, the message "Site time end" will be displayed on the screen. • If Site time heat is set to OFF in the setup, the sensor heat is switched off when the site timer reaches zero and the monitor stops monitoring; if set to ON, the heat continues.
3.	To mark an event, press ***Event***. The text "Set event mark number x?" will be displayed. Press ***OK*** to mark the event, or press ***Cancel*** to return to Normal view without marking the event. **NOTICE:** It is possible to mark up to 99 events.

Continued on next page

Patient monitoring (In vivo monitoring), *Continued*

Patient monitoring *(continued)*

Step	Action
4.	To link the session (i.e. the measurement in progress) to a specific patient ID, press ***ID*** in the top right corner of the view screens and make the necessary changes in the Patient DMS. For more information, see *Patient DMS* later in this chapter.
5.	View the readings and adjust the settings, if necessary. See chapter 3: *Menu structure and setup programs*.

WARNING – *Risk of skin damage*
Sensors must be moved to a new site at least every four hours. Because individual skin condition affects the ability of the skin to tolerate sensor placement, it may be necessary to change the sensor site more frequently with some patients. If skin integrity changes, move the sensor to another site.

WARNING – *Risk of incorrect measurements*
Always keep protection caps on the tcpCO_2/tcpO_2 sensors (except when applied to skin, placed in the calibration chamber or during handling and maintenance). Exposing sensor membranes to light (for example light from incubators) may cause elevated pCO_2 values.

NOTICE: After removing the sensor from the patient, make sure to wipe it clean from contact liquid before placing it in the calibration chamber.

Patient DMS

The Patient DMS (Data Management System) manages all session/patient ID data, and it helps avoiding the risk of patient data mix-up.

From the Patient DMS screen it is possible to:

- change the automatically generated session number to a unique patient ID
- view data from one or more sessions with the same ID in the Trend table or Trend curve view
- print one or more sessions
- export one or more sessions
- delete sessions
- see detailed information about a session

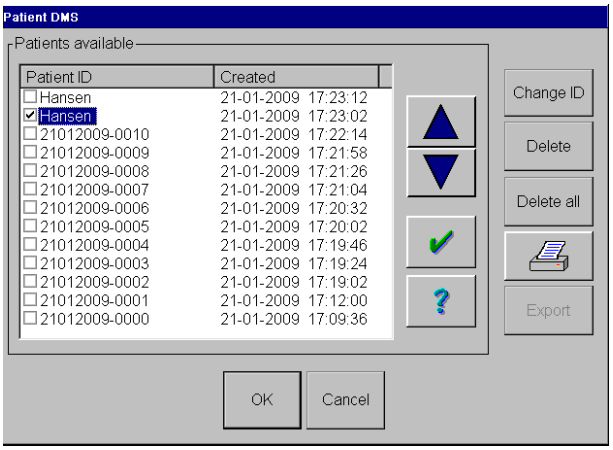
Session

A session is a collection of data starting when the sensor is removed from the calibration chamber and ending when the sensor is placed back in the calibration chamber.

Each session gets a unique number, which can be linked to a specific patient ID at any time. It is thereby possible to link several sessions to the same patient ID.

Accessing Patient DMS

Press ***ID*** in the top right corner of the view screens to enter the Patient DMS.



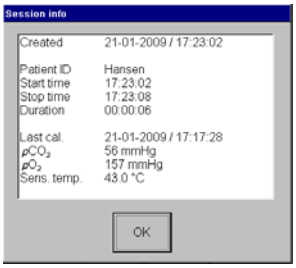
Touch keys

Touch key	Function
 and 	Scroll between the patient IDs/session numbers in the list.
	Adds a check mark to the highlighted patient ID/session no. **NOTICE:** Only patient IDs/session numbers with a check mark can be viewed, deleted, printed and exported.

Continued on next page

Patient DMS, *Continued*

Touch keys *(continued)*

Touch key	Function
	Shows detailed information about the highlighted patient ID/session number. 
Change ID	Enables changing the highlighted patient ID/session number with the on-screen alphanumeric keyboard (see next page). Maximum 64 characters. **NOTICE:** When changing a patient ID/session number, make sure to change it to something unique for each patient. If the same ID is used for two patients, the DMS will not be able to tell them apart.
Delete	Deletes the patient IDs/session numbers with a check mark. **NOTICES:** • A dialog warns users that the action cannot be undone. • The session in progress cannot be deleted.
Delete all	Deletes all patient IDs/session numbers in the list. **NOTICES:** • A dialog warns users that the action cannot be undone. • The session in progress cannot be deleted.
Print	Prints a report (one or more report types) for the patient IDs/session numbers with a check mark.
Export	Exports the patient information and measuring data for the patient IDs/session numbers with a check mark to an external PC or a memory stick (see the sections *Data export: serial* and *Data export: USB* later in this chapter). **NOTICE:** The ***Export*** touch key is only active if "Data export" has been selected in Technical settings.
OK	Loads sessions with a check mark into the Trend table and Trend curve views. **NOTICES:** • Only sessions with the same patient ID can be loaded into the same view. • If changes are made to the sessions that have been loaded into a view, all the sessions will have to be loaded into the view again.
Cancel	Returns to the view screen.

Continued on next page

Patient DMS, *Continued*

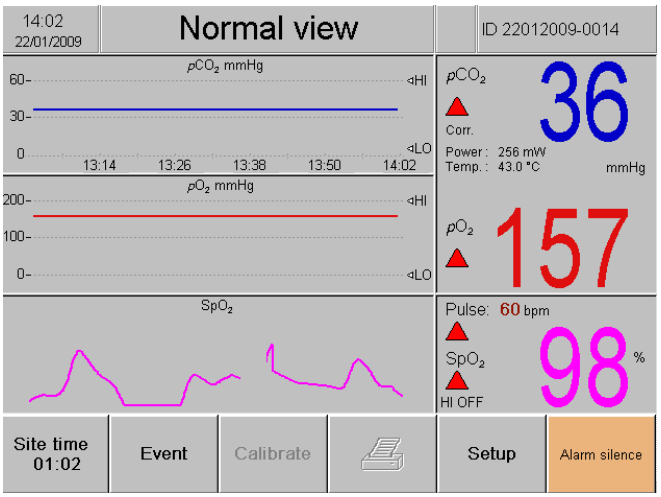
On-screen alphanumeric keyboard

The following screen shows the basic keyboard layout:

Touch Key	Function
	Escape. To return to the Patient DMS screen without making changes.
	To switch between general and language-specific character sets. Placed in the upper right corner of the screen. **NOTICE:** Not applicable in English.
	Backspace. To delete one character at a time from right to left.
	Shift. To shift between different keyboards in the same character set.
or	To scroll left/right in the text edit field.
	Space. To add a space.
	Enter. To accept the changes made in the text edit field and return to the Patient DMS screen.

Results in Normal view

Example of Normal view screen during monitoring

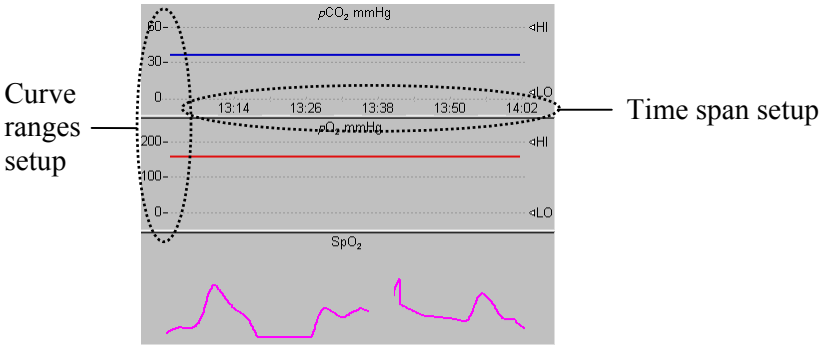


NOTICES:

- The SpO_2 plethysmograph displays data at a speed of 25 mm/s in Normal view.
- The visual indication of the plethysmograph curve is not proportional to the pulse volume.
- The pCO_2, pO_2, SpO_2 and Pulse parameter values are updated every 2 seconds.
- SpO_2 and pulse are available on the TCM40 monitor only.
- On the TCM4 monitor, the lower part of the curve display will either show the power curve or be empty, and the Pulse/SpO_2 display will always be empty.

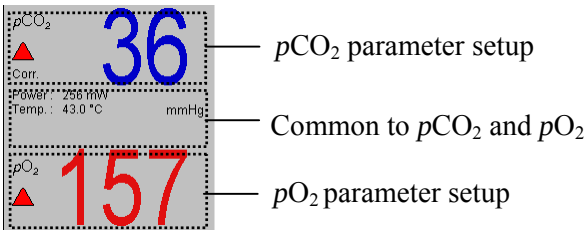
Curve display

In Normal view, it is possible to change the curve ranges setup and the time span setup during measurement by pressing the respective areas in the curve display.



pCO_2/pO_2 display

In Normal view, it is possible to change the parameter setup during measurement by pressing the respective areas in the pCO_2/pO_2 display.



Continued on next page

Results in Normal view, *continued*

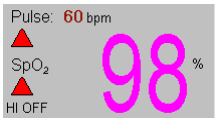
pCO_2/pO_2 display *(continued)*

The pCO_2/pO_2 display also contains the following information:

Part	Information
Corr.	Metabolic or Severinghaus corrections are enabled.
Power	Current power delivered to the sensor.
Temp.	Current sensor temperature. **NOTICE:** If the sensor temperature is flashing, the sensor temperature differs from the set sensor temperature with ±0.6 °C.
SmartHeat	SmartHeat has been enabled in the setup.
In vivo calibration active	Current pCO_2/pO_2 values are in vivo calibrated.

$Pulse/SpO_2$ display

In Normal view it is possible to change the $Pulse/SpO_2$ setup during measurement by pressing the $Pulse/SpO_2$ display.



The $Pulse/SpO_2$ display contains the following information:

Part	Information
Pulse	Pulse rate in beats per minute (bpm).
SpO_2	Saturation level of oxygenated hemoglobin in %.
HI OFF	SpO_2 alarm high limit is disabled.

Markings in Normal view

The following markings can be seen in Normal view:

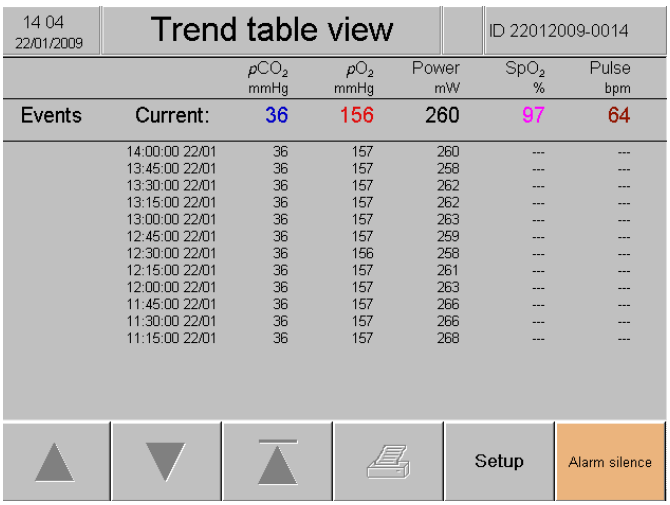
Marking	Information
♦	Blood gas values have been entered.
*	An in vivo calibration has been performed.
1-99	An event mark number has been added.

Results in Trend table view

Viewing results in Trend table view

Step	Action
1.	Press ***Setup → View → Trend table → OK.***

The following is an example of a trend table on a TCM40 monitor:



NOTICE: SpO_2 and pulse are available on the TCM40 monitor only.

2.	Press ▲ or ▼ to move up or down one line in the list of results, or press ⏫ to see the most recent results.
3.	To print the results, press ***Print***. See also *How to print* later in this chapter.

Markings in Trend table view

The following markings can be seen in the Trend table:

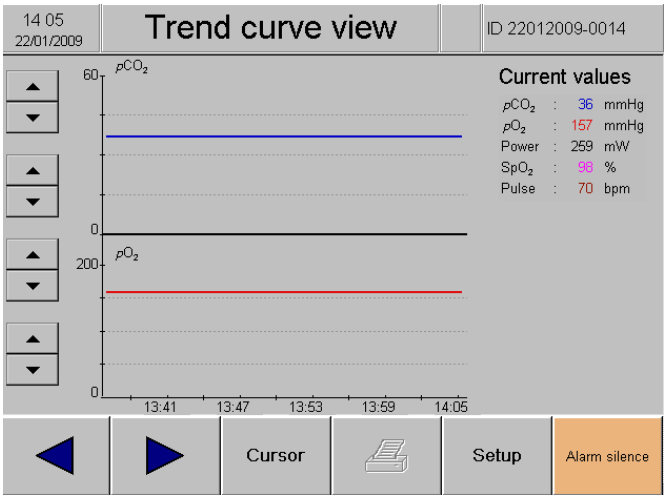
Marking	Indication
🩸	Blood gas values have been entered.
*	An in vivo calibration has been performed.
-	No value is available.
1-99	An event mark number has been added.

Results in Trend curve view

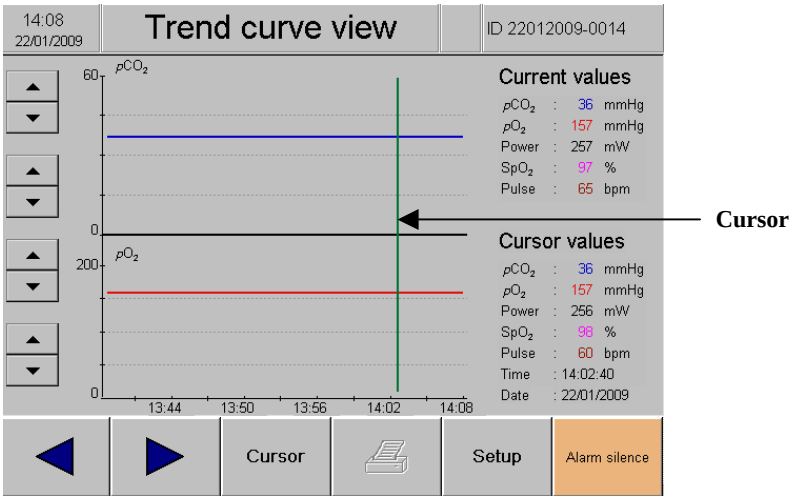
Viewing results in trend curve view

Step	Action
1.	Press ***Setup → View → Trend curve → OK.***

The following is an example of a trend curve on a TCM40 monitor:



2.	Press ◀ or ▶ to see more results to the left or the right.
3.	Press ***Cursor*** to add a cursor to the screen. This will also change the function of the ***Left*** and ***Right*** arrow keys: they now move the cursor instead of time. If the cursor is moved all the way to one side, the time axis moves, which makes it possible to go back and forth in time.



The cursor values (pCO_2, pO_2, Power, SpO_2, Pulse, Time and Date) are shown in the lower right part of the screen, whereas current values are shown in the upper right part of the screen.

Press ***Cursor*** again to remove the cursor from the screen.

Continued on next page

Results in Trend curve view, *Continued*

Viewing results in trend curve view *(continued)*

Step	Action
4.	To change the high or low values of the parameter ranges, press  .
5.	To print the results, press ***Print***. See also *How to print* later in this chapter.

Markings in Trend curve view

The following markings can be seen in the Trend curve view:

Marking	Indication
	Blood gas values have been entered.
*	An in vivo calibration has been performed.
-	No value is available.
1-99	An event mark number has been added.

Analog output

Introduction

The monitor is equipped with an output for direct connection to an external chart recorder or polysomnograph.

Setting up analog output

Follow the steps below to connect the TCM4/40 monitor to an external chart recorder or polysomnograph:

Step	Action
1.	Connect the TCM4xx ETX Analog Adapter (code no. 636-650) to the analog port. **NOTICE:** Do not use other adapters than 636-650.
2.	Connect the wires as follows:

Analog output	Wire color	Range
Ground	Blue	N/A
Alarm	Pink	Activated: 1000 mV, ±10 mV Not activated: 0 mV, ±10 mV
Heat	Brown	1 mV/mW @ 10-1000 mW, ±10 mV (±10 mW) < 10 mW ≈ 0 mV
Temp	Green	20 mV/°C @ 10-50 °C, ±10 mV (±0.50 °C)
tcpCO_2	Grey	10 mV/mmHg @ 0-100 mmHg, ±10 mV (±1 mmHg) 5 mV/mmHg @ 0-200 mmHg, ±10 mV (±2 mmHg)
tcpO_2	Yellow	5 mV/mmHg @ 0-200 mmHg, ±10 mV (±2 mmHg) 1 mV/mmHg @ 0-800 mmHg, ±10 mV (±10 mmHg)
SpO_2	White	10 mV/% SpO_2 @ 0-100 % (±1 % SpO_2)
Pulse	Red	4 mV/bpm @ 20-250 bpm ±10 mV (≈ ±3 bpm)

3.	On the monitor, press ***Setup*** → ***Technical***. Enter the password and press ***Enter*** and ***Tech. settings***.
4.	Use the ***Down*** arrow to select the pCO_2 analog range and choose the 0-100 or 0-200 range.
5.	Use the ***Down*** arrow to select the pO_2 analog range and choose the 0-200 or 0-800 range.
6.	Press ***OK*** to accept the changes and return to the main screen. **NOTICE:** To test the analog output, calibrate the monitor. When the calibration is complete, the analog output will correspond to the tcpCO_2 and tcpO_2 readouts on the display.

Continuous data output: standard

Introduction

The monitor is equipped with a continuous data output for direct connection to an external PC.

Connecting to external PC

Step	Action
1.	Connect the TCM4xx ETX Serial Adapter (code no. 636-649) to the serial port on the monitor and to the PC. The RS232 output from the monitor is transmitted continuously every 2 seconds in ASCII code in the following format: [Timestamp]; [O_2]; [CO_2]; [Heater power]; [Temperature]; [SpO_2]; [Pulse]
2.	On the monitor, press ***Setup*** → ***Technical***, enter the password and press ***Enter*** and ***Tech. settings***.
3.	Use the ***Up*** and ***Down*** arrows to select "Continuous data output" and choose the option "Standard".
4.	Press ***OK*** to accept the changes and return to the main screen.
5.	On the PC, select ***Start*** → ***Programs*** → ***Accessories*** → ***Communications*** → ***HyperTerminal*** and open the EXE file.
6.	Type in a name for the connection, e.g. TcData, and then click ***OK***.
7.	 Connect using COM1 and click ***OK***.

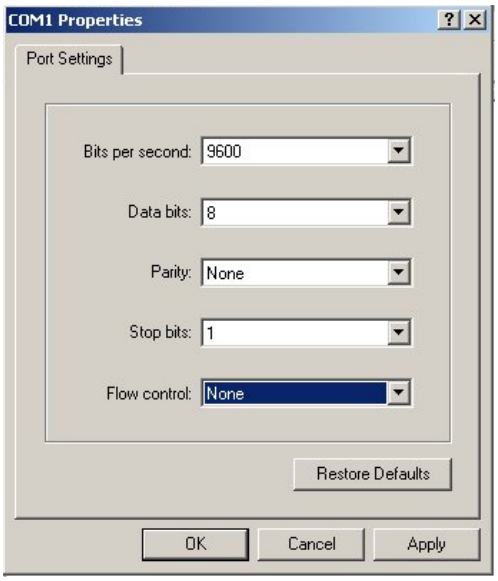
Continued on next page

Continuous data output: standard, *Continued*

Connecting to external PC *(continued)*

Step	Action

8. Select the following port settings and click ***OK***.

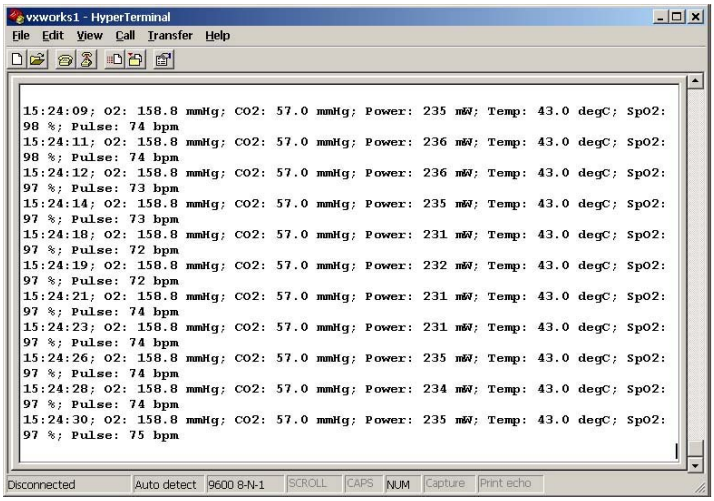


9. Collect the data in HyperTerminal by selecting ***Transfer*** → ***Capture text***.

Then name the file, e.g. CAPTURE.txt, and click ***Start***.

10. Stop the collection of data to the file in HyperTerminal by selecting ***Transfer*** → ***Capture text*** → ***Stop***.

The following shows a screen from HyperTerminal:



NOTICES:

- Data is easily imported into other programs, e.g. Microsoft Excel (see the procedure under *Data export: serial*).
- It is possible to have analog and serial output at the same time. The analog wires are short-circuit proofed.

Continuous data output: VueLink

Introduction

With a VueLink interface module type B, parameter values and attached alarm limit values can be exported from a TCM monitor to a Philips Patient Monitoring System (PPMS). The presentation of the data corresponds to Normal view.

NOTICE: Only the parameter values are displayed on the PPMS. The alarm limit values can only be used by a data management system connected to the PPMS.

Required items

- TCM4/40 monitors (software version 2.10 or newer)
- PPMS monitor (connected to one or more module racks)
- VueLink interface module type B (M1032A #A05)
- Connecting cable (Philips code no. M1032-61654) and TCM4xx ETX VueLink Adapter (Radiometer code no. 636-651) for connecting the VueLink interface module to the TCM monitor

NOTICE: In the following, the term PPMS includes the VueLink interface module.

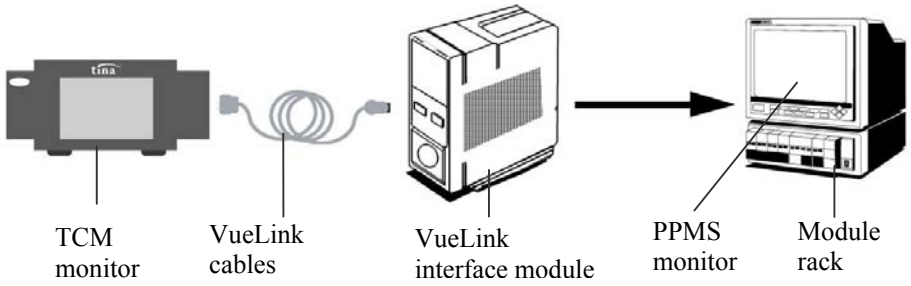
Possible PPMS monitors

The following patient monitors are supported:

- CMS (software version C or newer)
- IntelliVue MP40/50/60/70/90 (all software versions)
- Agilent V24/V26 (all software versions)

NOTICE: Older HP systems are often called CMS instead of PPMS.

Connecting to PPMS monitor



Step	Action
1.	Insert a VueLink interface module in the PPMS monitor module rack.
2.	Connect the VueLink interface module to the TCM monitor with the connecting cable and the VueLink interface cable.
3.	Turn on both monitors.
4.	On the TCM monitor, press ***Setup*** → ***Technical*** (enter password) → ***Tech. settings***, set "Continuous data output" to "VueLink" and press ***Apply*** or ***OK***. **NOTICE:** Changing settings for Unit will cause a temporary disconnection of communication of up to 60 seconds. The connection will be reestablished automatically.

Continued on next page

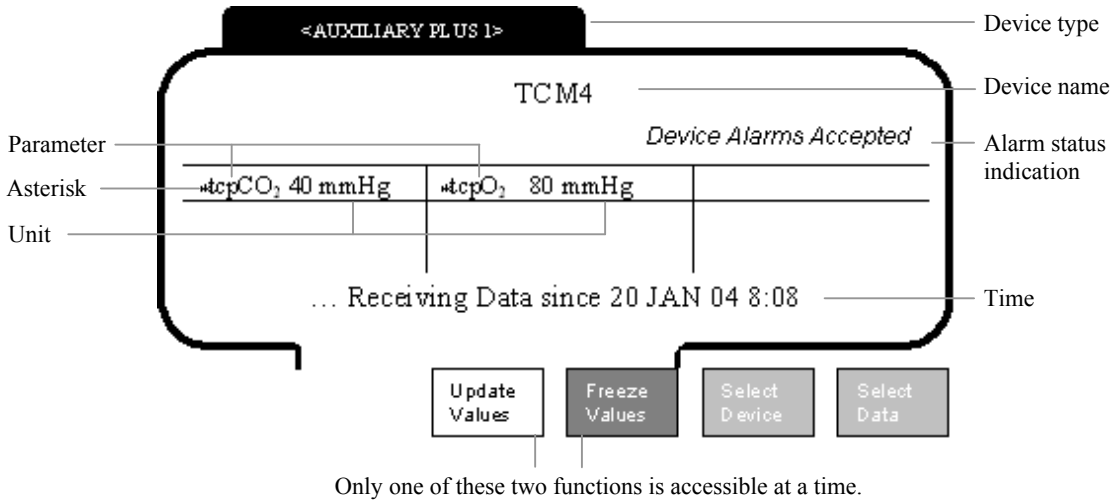
Continuous data output: VueLink, *Continued*

Verification of connection between TCM and PPMS monitors

Step	Action
1.	On the VueLink interface module, press the ***VueLink*** key. The "VueLink-B 1" tab appears on the PPMS monitor screen. **NOTICES:** • If the tab name is "AUXILIARY PLUS 1", connection to the module has already been established. • It is possible to insert several VueLink interface modules in the PPMS monitor, and they will then be called "VueLink-B 2", "VueLink-B 3", etc.
2.	Wait for the text "... Connect device or switch to new device" to disappear. **NOTICE:** If the text has not disappeared after 30 seconds, check the cable connection. If the cable connection is okay, see chapter 7: *Troubleshooting* for further operator actions.
3.	Select the ***Setup VueLink*** softkey. The "AUXILIARY PLUS 1" tab containing the parameter values from the TCM monitor appears.

Example of task window on PPMS monitor

The task window "AUXILIARY PLUS 1" is displayed automatically when connection between the TCM and the PPMS monitors has been established.



Continued on next page

Continuous data output: VueLink, *Continued*

Example of task window on PPMS monitor *(continued)*

NOTICES:

- Transmission of data from the TCM monitor to the PPMS monitor may be delayed with up to four seconds.
- Printout of data from the TCM monitor may cut off the connection between the TCM and the PPMS monitors while printing. The connection will be re-established automatically.
- For examples of other PPMS monitors, please refer to the user instructions for the relevant PPMS monitor.

The task window contains the following information:

Part	Shows
Device type	The type of connected module, e.g. AUXILIARY PLUS 1 (for the VueLink-B 1 module), AUXILIARY PLUS 2 (for the VueLink-B 2 module), etc.
Device name	The name of the connected TCM monitor, e.g. TCM4.
Alarm status indication	Whether alarms on the TCM monitor have been activated.
Parameter	The parameters exported from the TCM monitor.
Asterisk	That data for the following parameter is accessible on the main screen and in external databases.
Unit	The parameter units. **NOTICE:** Units are only shown in the task window.
Time	At which time the PPMS monitor started receiving data from the TCM monitor.

Main screen on PPMS monitor

The main screen is displayed by pressing the ***Main Screen*** key on the PPMS monitor.

The parameters are displayed at the bottom right-hand corner of the PPMS monitor screen:

Parameter on PPMS (TCM monitor)	Color on PPMS (TCM monitor)	Unit on PPMS and TCM monitors
tcpCO_2 (tc*p*CO_2)	Green (Blue)	mmHg/kPa
tcpO_2 (tc*p*O_2)	Green (Red)	mmHg/kPa
SpO_2 (SpO_2)	Green (Magenta)	%
PULSE (Pulse)	Green (Brown)	bmp

NOTICE: It is not possible to change the colors on the PPMS monitor.

Continued on next page

Continuous data output: VueLink, *Continued*

Configuration of PPMS monitor

Some features, keys or softkeys may vary from one monitor system to another, but the principles are basically the same. If you encounter differences between your system and what we describe in this manual, please see the technical documentation for the particular PPMS monitor.

The following configuration procedure is based on an Agilent V24C monitor.

Follow these steps to define how you want data presented on your PPMS monitor:

Step	Action
1.	Select the following softkeys: ***Module Setup*** → ***TCM*** (should have appeared when the TCM monitor was connected) → ***Select Data***.
2.	Mark the module number (***Num***) you wish to change with the up/down arrow keys.
3.	Select the ***Select Signal*** softkey.
4.	Select the ***Select Signal*** softkey again or use the left/right arrow keys to turn the signal ON (by selecting a parameter) or OFF.
5.	Select the ***Next Channel*** softkey.
6.	Repeat steps 2-5 for other modules you wish to change.
7.	Press the ***Main Screen*** key to finish and to display the selected signals.

Alarms

VueLink defines two types of alarms: red and yellow; but a TCM monitor only gives yellow alarms.

A **yellow** alarm indicates a situation where a response of the medical staff is necessary, but which is of less critical importance than a red alarm.

An alarm is displayed as a text on a yellow background at the top center of the PPMS monitor screen, e.g. "TC ALARM", which means that an alarm limit has been exceeded. Details about the specific alarm condition can be seen on the TCM monitor.

Alerts

Alerts are caused by errors related to the TCM monitor or its accessories.

An alert is displayed as a text on a green background at the top left-hand corner of the PPMS monitor screen.

The following alerts may be displayed on the PPMS monitor screen:

Alert	Interpretation
SEE TC MONITOR	Details about the specific alert condition can be seen on the TCM monitor.
TC BAT LOW	Necessary to connect to mains.

Continued on next page

Continuous data output: VueLink, *Continued*

Alerts *(continued)*

Depending on the alert, parameter values may be displayed in the following ways:

Parameter reading	Interpretation
? (parameter value)	Data may be wrong
-?-	Provided data is wrong
(Blank)	No data can be provided

NOTICE: Alarm/alert delays between the PPMS and TCM monitors are less than two seconds.

Troubleshooting

Symptom	Cause	Recommended action(s)
It is not possible to establish contact between the TCM and PPMS monitors	Error related to physical connection	• Check that both monitors are ON • Check the cable connection • If error remains, contact authorized service personnel
	Incorrect installation of TCM monitor	• Check that the TCM monitor is set up for VueLink transmission • If error remains, contact authorized service personnel
	Incorrect installation of PPMS monitor	• Reset the PPMS to factory defaults, or • Select ***Module Setup*** and set "AUXILIARY PLUS 1" or "VueLink-B" to "ON" • If error remains, contact authorized service personnel

Continuous data output: MonLink

Introduction

Enables TCM transmission of real-time data to external equipment. Any interaction is initiated by host request that includes:

Request	Reply
Status	System/parameter status
Measuring values	Measuring values and system/parameter status
Parameter ranges	Analog ranges, selected alarm ranges and parameter alarm status

Available measured parameters

TCM configuration	Parameter				
	pCO_2	pO_2	SpO_2	PR	Power
TCM4 monitor	x	x			x
TCM40 monitor	x	x	x	x	x

Detailed alarm and alert notifications are not communicated but have to be revealed on the TCM monitor display.

All data values are updated every 2 seconds. How status and measured values are presented is decided by and is under the responsibility of the vendor of the external equipment.

NOTICE: For information on alarm delay and source/identification on external equipment, please refer to the user instructions for the relevant external equipment.

Detailed communication protocol

For the detailed communication protocol, please see the document *TCM Communication Protocol Specifications* (code no. 994-038) from Radiometer.

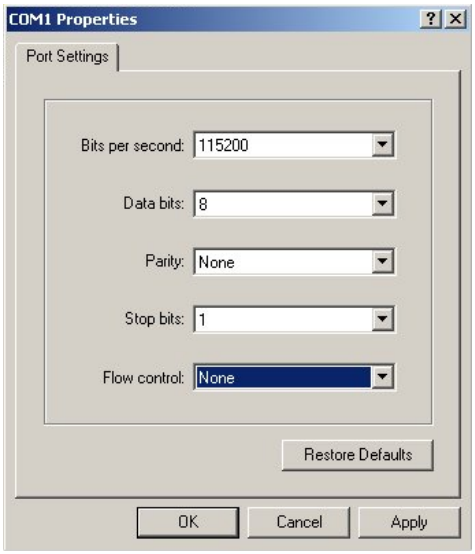
Data export: serial

Introduction

With the data export option, a dump of the trend data can be exported to an external PC and presented in spreadsheet format.

Exporting data to PC

In this example, HyperTerminal version 690170 with Excel version 97 SR-2 is used.

Step	Action
1.	Connect the TCM4xx ETX Serial Adapter (code no. 636-649) to the serial port on the TCM monitor and to the PC.
2.	On the PC, select ***Start*** → ***Programs*** → ***Accessories*** → ***Communications*** → ***HyperTerminal*** and open the EXE file.
3.	Type in a name for the connection, e.g. TcData, and click ***OK***.
4.	 Connect using COM1 and click ***OK***.
5.	Select the following port settings and click ***OK***. 

Continued on next page

Data export: serial, *Continued*

Exporting data to PC *(continued)*

Step	Action
6.	Collect the data in HyperTerminal by selecting ***Transfer*** → ***Capture text***. Then name the file, e.g. CAPTURE.txt, and click ***Start***.
7.	On the TCM monitor, press ***Setup*** → ***Technical***, enter password and press ***Enter*** and ***Tech. settings***.
8.	Set "Continuous data output" to "OFF", "Data export" to "Serial" and "Data export interval" to 2, 10, 30 or 60 seconds. Then press ***OK***. The data is exported to HyperTerminal and can be seen on the PC.
9.	On the PC, stop the collection of data to the file in HyperTerminal by selecting ***Transfer*** → ***Capture text*** → ***Stop***. The following shows an extract of a screen from HyperTerminal:

```
TCM4/40 Data Export
15:25:25 30/11/07 - 15:26:56 30/11/07

Patient ID: 30112007-0015

Last calibration: 15:24:53 30/11/07 - O2 : 157 mmHg - CO2 : 56 mmHg

Time;Event;O2 mmHg;CO2 mmHg;Temp °C;Power mW;SpO2 %;Pulse bmp;
15:25:30 30/11/07;;70 ;38 ;42.0;227 ;98;71;
15:25:40 30/11/07;;71 ;38 ;42.0;227 ;97;72;
15:25:50 30/11/07;;71 ;38 ;42.0;228 ;98;71;
15:26:00 30/11/07;;71 ;38 ;42.0;228 ;98;72;
15:26:10 30/11/07;;70 ;38 ;42.0;227 ;98;71;
15:26:20 30/11/07;;70 ;38 ;42.0;228 ;98;72;
15:26:30 30/11/07;;71 ;38 ;42.0;228 ;97;71;
15:26:40 30/11/07;;70 ;38 ;42.0;227 ;98;72;
15:26:50 30/11/07;;70 ;38 ;42.0;227 ;98;71;
```

Importing data files into Microsoft Excel

Step	Action
1.	Open Excel and select ***Data*** → ***Get External Data*** → ***Import Text File***.
2.	Select the file CAPTURE.txt and click ***Import***.
3.	Select the following settings and click ***Next***.

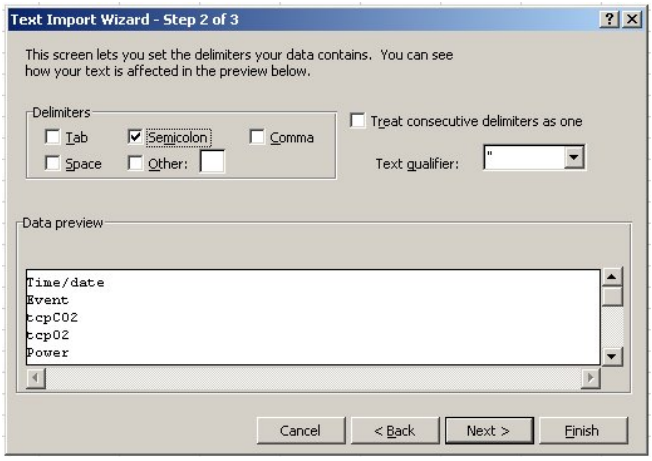
Continued on next page

Data export: serial, *Continued*

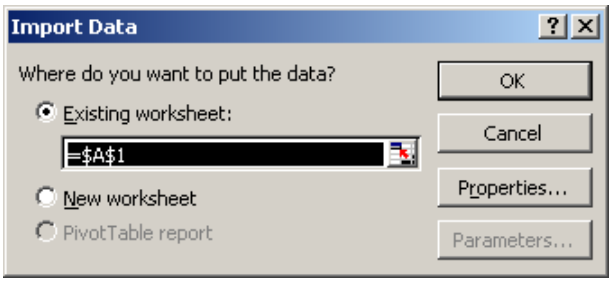
Importing data files into Microsoft Excel *(continued)*

Step	Action

4. Select the following settings and click ***Finish***.

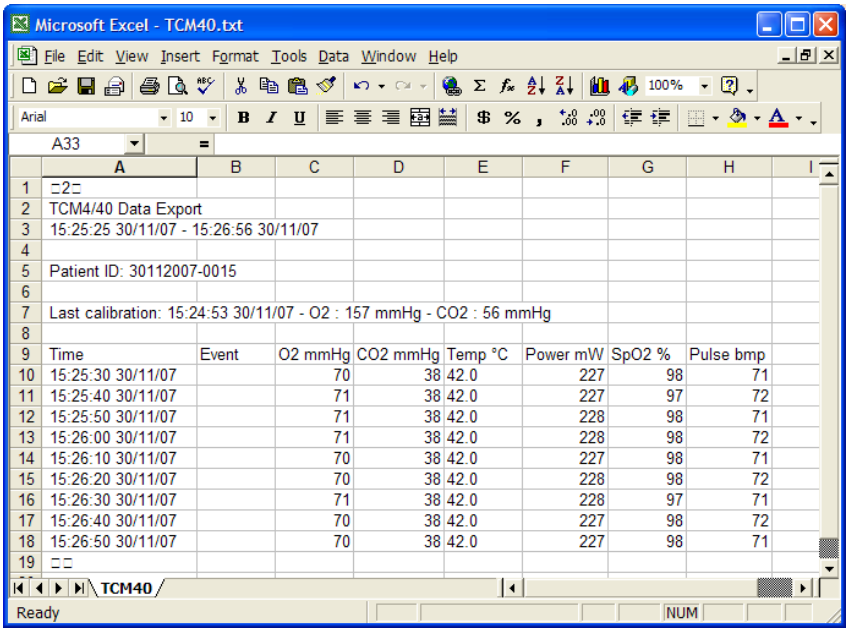


5. Select the following settings and click ***OK***.



6. Data is imported to Excel.

The following shows an extract of a screen from Excel:



7. Save (Log Excel worksheet).

Data export: USB

Introduction

With this option, patient information and a dump of the trend data can be exported to a memory stick through one of the USB ports.

Exporting data to a memory stick

Step	Action
1.	Connect a memory stick to one of the USB ports on the TCM monitor.
2.	Press ***Setup*** → ***Technical*** *(enter password and press* ***Enter****)* → ***Tech. Settings***.
3.	Set "Data export" to "USB" and "Data export interval" to 2, 10, 30 or 60 seconds. Then press ***OK***.
4.	Press ***ID*** to access Patient DMS.
5.	Select the patient ID(s)/session(s) to export and press ***Export***. The selected data will be exported to the USB port. **NOTICES:** • If a memory stick is not connected to the monitor, a dialog box will be displayed, asking the user to insert a USB storage device. The user can either cancel the data export by pressing ***Cancel*** or insert a memory stick and press ***OK*** to initiate the data export. • While data is being exported, a status dialog will be displayed. It will not be possible to operate the monitor until the export of data has been completed. Removing the memory stick before the data export has been completed will result in incomplete data export.

Alarms

Purpose

The alarm system informs the user about physiological and technical errors, or it gives text messages about recommended actions.

NOTICE: Every time the monitor is turned on, it performs a test of the alarm system to check that the sound is working.

Definitions

The alarm system contains three different "alarms":

- Alarms = physiological alarms: one or more of the parameter values have exceeded or are equal to the high or low alarm limits
- Alerts = technical alarms: inform the user if e.g. an error has been detected during calibration
- Messages = pure text, e.g. "Ready"

Alarms

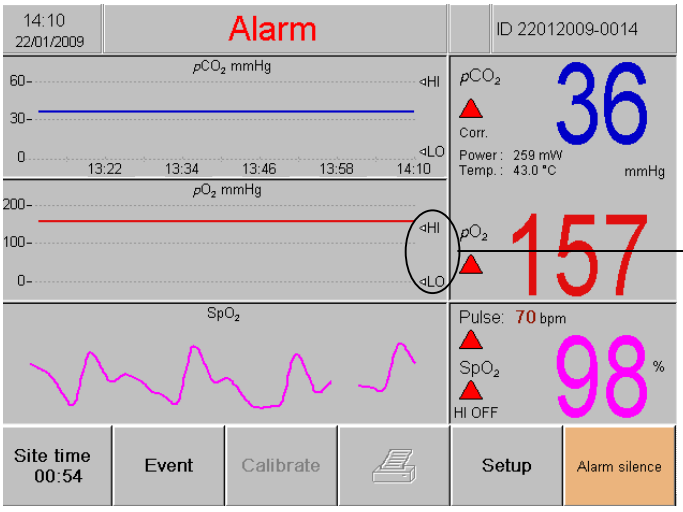
Alarms are enabled/disabled in Parameter setup.

NOTICE: If the  symbol is displayed on the screen, all visual and acoustic alarm indications are disabled. Alerts are not affected.

It is possible to choose between two modes (see Technical settings in chapter 3: *Menu structure and setup programs*):

- Latching: The monitor remains in alarm status even though the alarm condition ceases to exist. So even if all parameter values are back within the alarm limits, the user must reset the alarm.
- Non-latching: The monitor resets itself as soon as the alarm condition ceases to exist.

An alarm is made up of visual indications (the parameter value and an alarm text will be flashing) and an acoustic indication (a discontinuous tone).



Alarm limit symbols

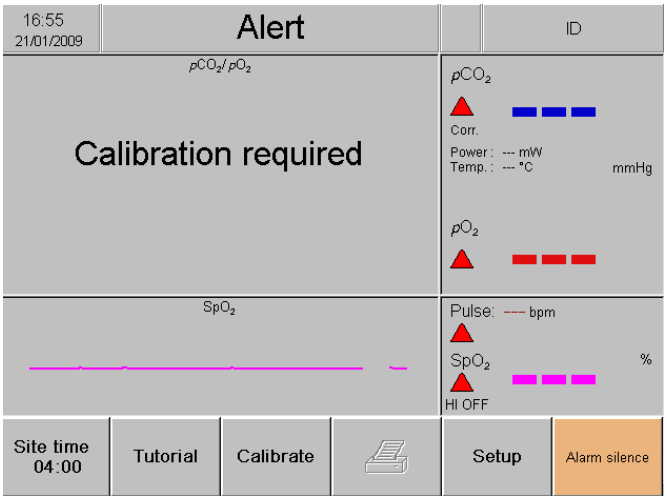
Continued on next page

Alarms, *Continued*

Alerts

An alert cannot be turned off but disappears automatically when the alert condition ceases to exist.

An alert is made up of visual indications ("Alert" displayed in the headline field and a text explaining the problem in the curve view field of the affected parameter) and an acoustic indication (a discontinuous tone).



Alarm silence

It is possible to silence an alarm or an alert for two minutes by pressing the ***Alarm silence*** touch key. A progress bar will then be displayed on the ***Alarm silence*** touch key, showing the progress of the alarm silence period. However, if an alarm/alert is activated for another parameter during the silence period, this will discontinue the silence period and activate the alarm/alert sounds.

NOTICE: When affixing the sensor to the patient, i.e. when the monitor goes from Ready to Measuring mode, the alarm silence period starts automatically and lasts for 10 minutes.

Alarm reset

When the alarm silence period times out, the alarm system is reset.

The alarm system can also be reset by pressing the ***Alarm silence*** touch key twice (or once, if the alarm silence is already activated).

If the alarm/alert condition is still present when the alarm system is reset, the visual indications will remain for both types of alarms, whereas the acoustic indication will be reactivated for an alarm condition only.

Alarm tone

An alarm tone consists of bursts of 10 short pulses. Between two bursts there is a 3-second pause. The alarm tone continues until the alarm condition ceases to exist or Alarm silence is activated.

Continued on next page

Alarms, *Continued*

Alert tone

An alert tone consists of two pulses followed by a 5-second pause. The alert tone continues until the alert condition ceases to exist or Alarm silence is activated.

End-of-calibration tone

An End-of-calibration tone consists of two pulses.

TCM40 SatSeconds

With traditional alarm management, upper and lower alarm limits are set for monitoring oxygen saturation. During monitoring, as soon as an alarm limit is violated by as little as one percentage point, an audible alarm immediately sounds. When the SpO_2 level fluctuates near an alarm limit, the alarm sounds each time the limit is violated. Such frequent alarms can be distracting.

Therefore, the TCM40 SpO_2 module utilizes SatSeconds alarm management. With the SatSeconds technique, upper and lower alarm limits are set in the same way as traditional alarm management. However, the clinician also sets a SatSeconds limit that allows monitoring of SpO_2 below the selected lower alarm limit and above the selected upper alarm limit for a period of time before an audible alarm sounds.

The SatSeconds limit controls the time that the SpO_2 level may violate the alarm limits before an audible alarm sounds. SatSeconds is enabled/disabled in SpO_2 parameter setup.

The method of calculation is as follows:

The number of percentage points that the SpO_2 falls outside the alarm limit is multiplied by the number of seconds that the SpO_2 level remains outside that limit. This can be stated as an equation:

points × seconds = SatSeconds

where:

- points = SpO_2 percentage points outside of the limit
- seconds = number of seconds that SpO_2 remains at that point outside of the limit

The alarm response time, assuming a SatSeconds limit set at 60 and a lower alarm limit set at 90, is described and illustrated below.

In this example, the SpO_2 level drops to 88 (2 points) and remains there for a period of 2 seconds (2 points × 2 seconds = 4). The SpO_2 then drops to 86 for 3 seconds and then to 84 for 8 seconds. The resulting SatSeconds are:

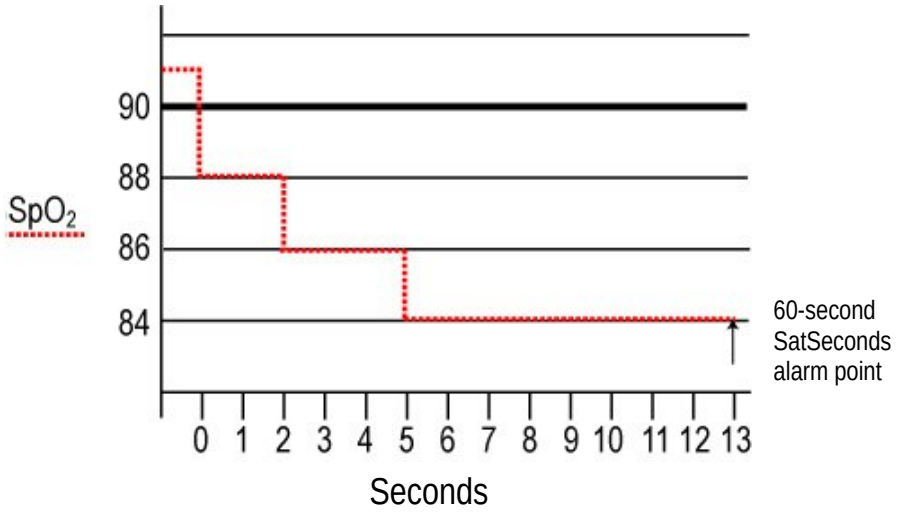
SpO_2	Seconds	SatSeconds
2 ×	2 =	4
4 ×	3 =	12
6 ×	8 =	48
	Total SatSeconds =	64

Continued on next page

Alarms, *Continued*

TCM40 SatSeconds *(continued)*

After approximately 13 seconds, the SatSeconds alarm will sound, because 60 SatSeconds will have been exceeded. See arrow (↑) in the figure below.



Saturation levels may fluctuate rather than remain steady for a period of several seconds. Often, SpO_2 levels may fluctuate above and below the alarm limit, re-entering the non-alarm range several times.

During such fluctuation, the TCM40 monitor integrates the number of SpO_2 points, both positive and negative, until either the SatSeconds limit (SatSeconds setting) is reached or the SpO_2 level returns to within a normal range and remains there.

SatSeconds "safety net"

The SatSeconds "safety net" is for patients whose saturation levels frequently exceed the high or low alarm limit but do not stay outside the limit long enough for the SatSeconds setting to be reached. When three or more limit violations occur in 60 seconds, an alarm will sound even if the SatSeconds setting has not been reached.

How to print

Connecting a printer

Step	Action
1.	Shut down the monitor by following the procedure described in chapter 4: *Installation and maintenance*.
2.	Connect an HP printer with PCL3 protocol to one of the USB ports on the rear of the monitor.
3.	Switch on the monitor.

Printing reports

Step	Action
1.	If required, go into Printer setup to change the printer settings (see chapter 3: *Menu structure and setup programs*).
2.	Press ***Print*** and set the printer start and stop times. **NOTICES:** • The monitor must be connected to a printer with PCL3 protocol. • The memory function holds a total of 48 hours of monitoring data. • The printed report will be performed in accordance with the printer settings selected in the printer setup. • The time span selected in the printer setup will influence the start time of the Printer start/stop time screen, as the interval between the printer start and stop times corresponds to the time span; i.e. if the time span is set to 1 hour, the interval between the printer start and stop times will also be 1 hour (See *Printer setup* in chapter 3). • The scroll interval depends on the time span selected in the printer setup. If the time span is set to less than 1 hour, the scroll interval will correspond to the exact time span (e.g. 5, 15 or 30 min). If the time span is set to 1 hour or more, the scroll interval will be 1 hour. • The stop time is set to current time and then adjusted to match the time of the latest data record. The stop time can therefore differ from current time with up to 2 hours, depending on the time interval selected in the printer setup.
3.	Press ***OK*** to make a printout, or press ***Cancel*** to exit the dialog box without making a printout. **NOTICES:** • The different kinds of event marks are only shown on the printout if they are actually present. • Even if both report types are selected in Printer setup, there will only be one "Comments" page.

Continued on next page

How to print, *Continued*

Example of table report

RADIOMETER TCM4 SERIES

Transcutaneous measurement (tcpCO_2/tcpO_2/SpO_2/Pulse)

Measuring unit:	tcpCO_2/tcpO_2	mmHg	Sensor temperature:		42.0 °C
	Power	mW	Last calibration		01:27:07 02/03/2004
	SpO_2	%	Last calibration value:	pCO_2	80 mmHg
	Pulse	bpm		pO_2	160 mmHg

Facility name:_____

Patient name/ID:_____

Blood gas event mark * In vivo calibration - No value available

Time/date	Event	tcpCO_2	tcpO_2	Power	SpO_2	Pulse
02:23:00 02/03/04		34	158	3	97	71
02:24:00 02/03/04		34	158	7	97	71
02:25:00 02/03/04	1	34	158	11	97	71
02:26:00 02/03/04		34	158	-	97	71
02:27:00 02/03/04		-	158	16	96	70
02:28:00 02/03/04	2	34	158	19	96	70
02:29:00 02/03/04		34	158	23	97	72
02:29:13 02/03/04		-	-	-	97	72
02:30:00 02/03/04		34	158	26	97	72
02:31:00 02/03/04	3	34	158	30	97	72
02:32:00 02/03/04		34	158	31	97	72
02:33:00 02/03/04		34	158	33	97	72
02:34:00 02/03/04		34	158	37	97	72
02:35:00 02/03/04		34	158	-	97	72
02:36:00 02/03/04		-	158	40	97	72
02:37:00 02/03/04		34	158	43	97	72
02:38:00 02/03/04		34	158	46	97	72
02:39:00 02/03/04		34	158	51	97	72
02:40:00 02/03/04		34	158	52	97	72
02:41:00 02/03/04		34	158	52	97	72

Printed: 02:53:07 02/03/2004 Page 1

Continued on next page

How to print, *Continued*

Example of table report *(continued)*

RADIOMETER TCM4 SERIES

Transcutaneous measurement (tcpCO_2/tcpO_2/SpO_2/Pulse)

Facility name:_____

Patient name/ID:_____

Comments:_____

Physician's signature:_____ Date:_____

Printed: 02:53:07 02/03/2004 Page 2

Continued on next page

How to print, *Continued*

Example of curve report

RADIOMETER TCM4 SERIES

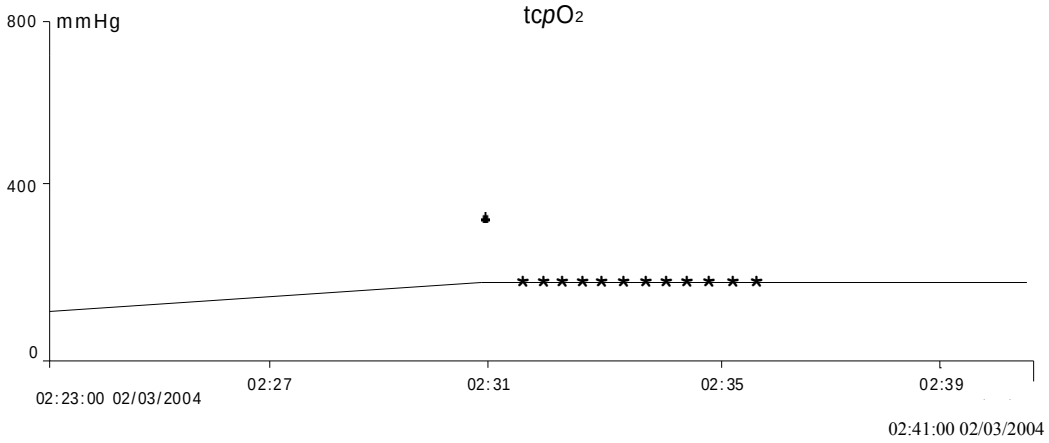
Transcutaneous measurement (tcpCO_2/tcpO_2/SpO_2/Pulse)

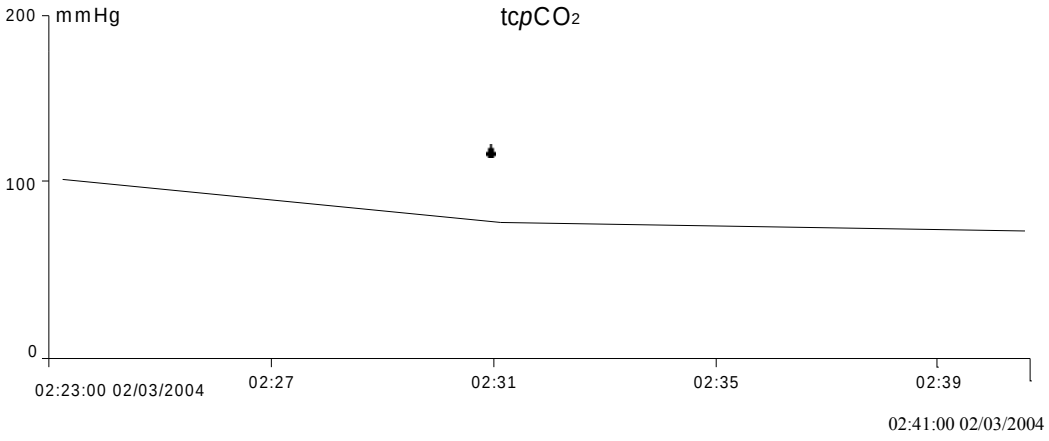
Measuring unit:	tcpCO_2/tcpO_2	mmHg	Sensor temperature:		42.0 °C
	Power	mW	Last calibration		01:27:07 02/03/2004
	SpO_2	%	Last calibration value:	pCO_2	80 mmHg
	Pulse	bpm		pO_2	160 mmHg

Facility name:_____

Patient name/ID:_____

Blood gas event mark * In vivo calibration





Printed: 02:53:07 02/03/2004 Page 1

Continued on next page

How to print, *Continued*

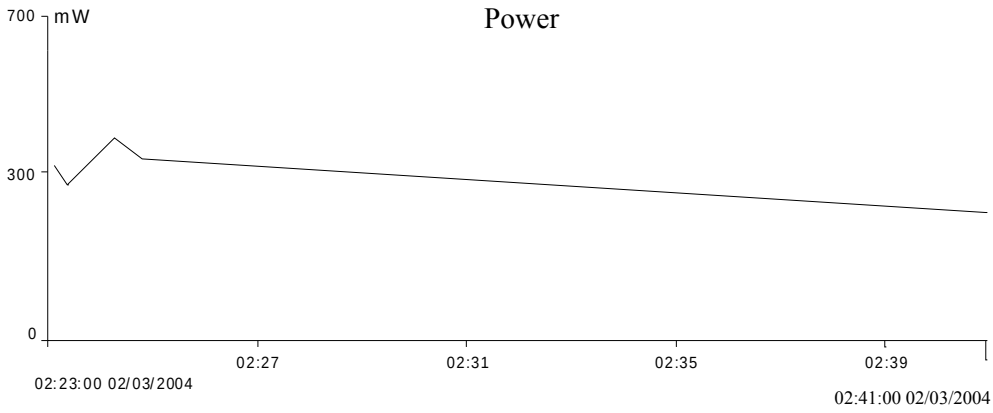
Example of curve report *(continued)*

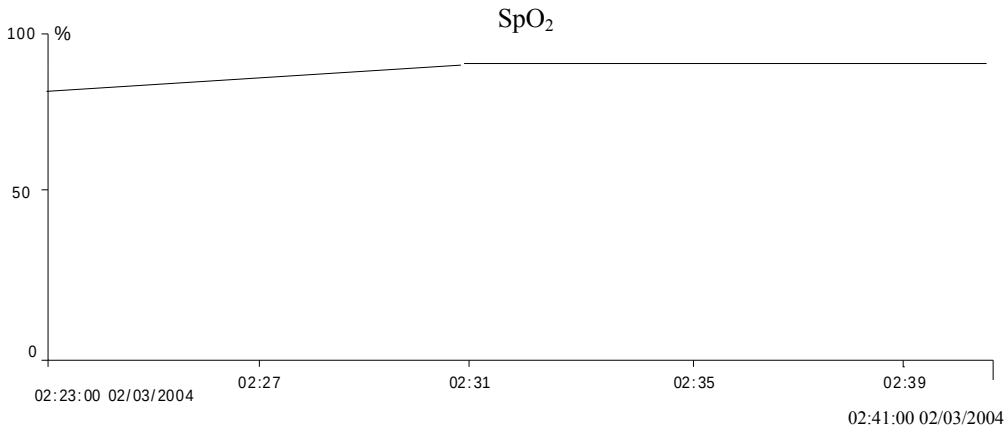
RADIOMETER TCM4 SERIES

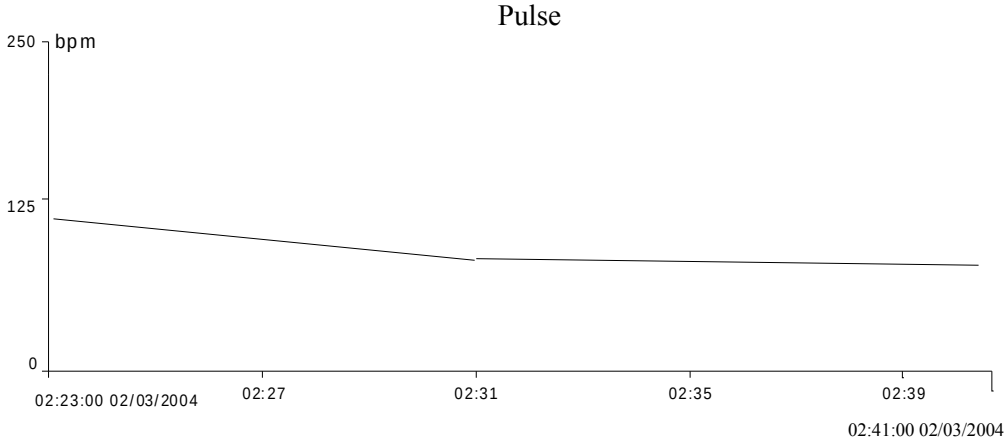
Transcutaneous measurement (tc*p*CO_2/tc*p*O_2/SpO_2/Pulse)

Facility name:_____

Patient name/ID:_____







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Continued on next page

How to print, *Continued*

Example of curve report *(continued)*

RADIOMETER TCM4 SERIES

Transcutaneous measurement (tcpCO_2/tcpO_2/SpO_2/Pulse)

Facility name:_____

Patient name/ID:_____

Comments:_____

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Physician's signature:_____ Date:_____

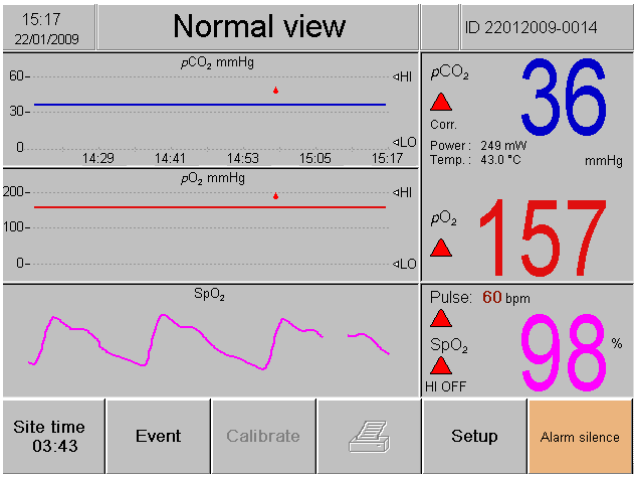
Blood gas comparison

Introduction

It is possible to key in the pCO_2 and pO_2 blood gas values of a patient to compare these with transcutaneous measurements from the same patient. The blood gas values are displayed as blood drops in all views as well as on all printed reports.

Keying in blood gas value

Step	Action
1.	Make sure that the sensor is placed on the patient and that the tcpCO_2 and tcpO_2 values are stable.
2.	Before drawing the blood sample, press ***Setup*** → ***Parameter*** → ***Blood gas*** → ***Sample time***. The monitor will store the tc values at that time and the pCO_2 and pO_2 input fields and the numeric keypad are now accessible.
3.	Draw the blood sample and perform a blood gas analysis.
4.	When the blood gas results are ready, enter the Blood gas setup, press the pCO_2 input field and key in the value with the numeric keypad. **NOTICES:** • The ***l***-- key deletes one character at a time from the right. • If the pCO_2 or pO_2 input field is dimmed, the parameter is not available, either because of the sensor type or because pO_2 is disabled in Technical setup.
5.	Press the pO_2 input field and key in the value with the numeric keypad, and then press ***OK***. The blood gas values will be displayed as blood drops in Normal view as in the following example:



In vivo calibration

Introduction

It is possible to perform in vivo calibrations, i.e. alterations in the transcutaneous readings, using the results from an arterial blood gas analysis. In vivo calibrations can either be performed on pCO_2, pO_2 or both parameters.

When the blood gas values have been entered on the TCM4/40 monitor, the new calibration lines are calculated.

The following formulas are used:

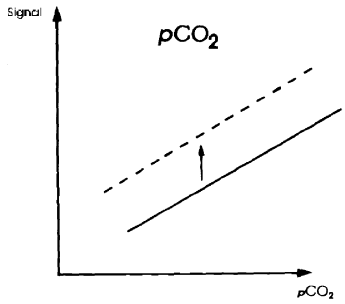
$tcpCO_2(corr) = tcpCO_2 + [pCO_2(a) - tcpCO_2(t)]$

$tcpO_2(corr) = tcpO_2 \times [pO_2(a) / tcpO_2(t)]$

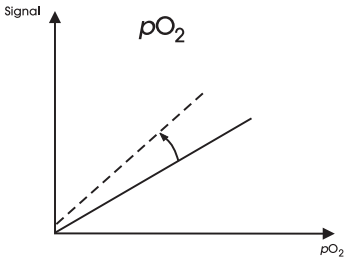
where

- $tcpCO_2$ is either the measured CO_2 value or the measured CO_2 value with correction (if corrections are selected in Technical settings)
- $pCO_2(a)$ and $pO_2(a)$ are the measured arterial values
- $tcpCO_2(t)$ and $tcpO_2(t)$ are the transcutaneous values measured at time t, which is the approximate time when the arterial sample was taken and the ***Sample time*** touch key was pressed.

On the pCO_2 part, the corrected (CORR) value line will have the correct (45°) slope. The in vivo calibration, therefore, gives an offset for all values – i.e. it moves the line – just as changing the metabolic factor in Technical settings would do.



On the pO_2 part of the sensor, the in vivo calibration changes the sensitivity (the slope) of the pO_2 signal, just as with normal calibrations.



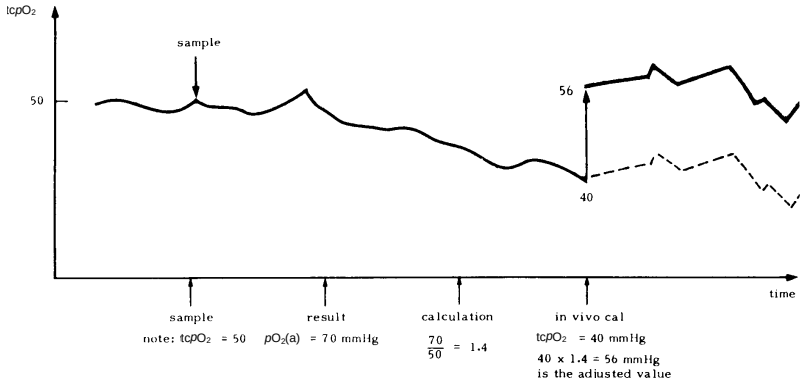
Continued on next page

In vivo calibration, *Continued*

Introduction *(continued)*

NOTICES:

- In vivo calibration should not be performed on hemodynamically unstable patients, because the arterial blood gas value and the tc value may fluctuate considerably.
- In vivo calibration of a tc value will bring the displayed value closer to the arterial sample reading. But the correlation between the tc and the arterial values will remain unchanged.
- In vivo calibration does not make the TCM monitor read arterial values. Nor does it eliminate the blood flow dependence on the tc value or any of the other determinants. It gives the same information as the original tc value – only on another level (see the graph below).



Performing an in vivo calibration

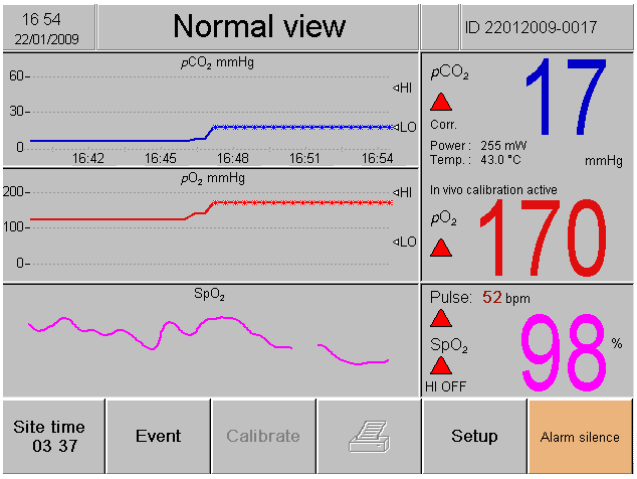
Step	Action
1.	Make sure that access to the ***In vivo calibration*** touch key has been enabled in Technical settings, that the sensor is placed on the patient and that the tc values are stable.
2.	Before drawing the blood sample, press ***Setup*** → ***Parameter*** → ***Blood gas*** → ***Sample time***. The monitor will register the blood sampling time and the pCO_2 and pO_2 input fields and the numeric keypad are now accessible.
3.	Draw the blood sample and perform a blood gas analysis.
4.	When the blood gas result is ready, enter the Blood gas setup, press the pCO_2 input field and key in the value with the numeric keypad.
5.	Then press the pO_2 input field and key in the pO_2 value.
6.	Press ***In vivo calibration*** and ***OK***.

Continued on next page

In vivo calibration, *Continued*

Performing an in vivo calibration *(continued)*

Step	Action
	The curves will now be marked with *, indicating that the measured values are in vivo calibrated and no longer show the original transcutaneous values.



NOTICES:

- The in vivo calibration procedure can be repeated during the monitoring period if you wish to alter the values again according to the results of new blood samples.
- To return to the original tc values, simply put the sensor back in the calibration chamber.

7. Troubleshooting

The TCM4/40 systems

Introduction

The monitor contains Radiometer-developed software that has been developed, tested and released according to our certified Quality Assurance System in order to minimize hazards arising from the software. Furthermore, the status of the system is continuously monitored during operation. Should a problem or error occur, it is automatically recorded and presented to the operator on the screen.

This chapter describes possible errors, their causes and the recommended operator actions.

NOTICE: The monitor cover should be removed only by authorized service personnel. There are no user-serviceable parts inside.

Error symptoms

Symptom	Cause	Recommended action(s)
Monitor not operational	• Monitor is defective • Battery is exhausted • Monitor is not connected to mains	• Check the connections • Contact authorized service personnel
Measured values drift when sensor is measuring on cal gas (in vitro)	• Insufficient removal of old electrolyte during membraning procedure • Air bubbles in electrolyte • The sensor membrane has not been changed regularly • Defective sensor membrane (holes or scratches) • Defective O-rings (one or both O-rings are broken)	• Remembrane the sensor • Check sensor zero current and sensitivity
Measured values drift constantly without any clinical cause when sensor is mounted on patient (in vivo)	• Improper attachment of the sensor • Improper attachment of the fixation ring • An inappropriate measurement site has been selected • Inadequate vasodilation	• Detach the sensor and reapply correctly • Detach the fixation ring and reapply correctly • Check sensor zero current and sensitivity
	• Hole in the membrane • Air under the membrane	Remembrane the sensor

Continued on next page

The TCM4/40 systems, *Continued*

Error symptoms *(continued)*

Symptom	Cause	Recommended action(s)
Measured values not stable or out of range 20 minutes after application	• Patient status unstable • Inadequate vasodilation • Improper attachment of the sensor	• Evaluate patient status • Remount the sensor
	• Sensor exposed to high ambient light • Hole in the membrane • Air under the membrane	Remembrane the sensor
Measured values change suddenly without any clinical cause	• Inaccurate result due to patient movements • Air leakage under fixation ring • Self-adhesive ring does not stick to the skin	Recalibrate and reapply sensor to the skin, possibly selecting a new measuring site
	• Hole in the membrane • Air under the membrane	Remembrane the sensor
Noise appears on the tension readout	Interference from nearby equipment	Increase the distance from the interfering equipment

Monitor error message

Error message	Cause	Recommended action
Battery level low	Battery level is low	Connect the monitor to the mains

tc error messages – in alphabetical order

Error message	Cause	Recommended action(s)
Calibration error. Barometer error during calibration.	Barometer value invalid when collected at start of calibration	• Start a new calibration • If error remains, contact authorized service personnel
Calibration error. Gas flow out of range.	• Calibration chamber is blocked • Calibration unit is defective	• Check chamber sealing • Contact authorized service personnel
Calibration error. Gas level low.	Less than 10 calibrations left	Change gas bottle

Continued on next page

The TCM4/40 systems, *Continued*

tc error messages – in alphabetical order *(continued)*

Error message	Cause	Recommended action(s)
Calibration error. Leak error in calibration chamber.	There is a leak in the calibration chamber	• Check that a gasket is present and positioned correctly in the chamber • Check that the sensor is positioned correctly in the chamber
Calibration error. No sensor connected to the chamber.	No sensor detected in the calibration chamber at start of or during calibration	Place a tc*p*CO_2/tc*p*O_2 sensor in the chamber
Calibration error. Sensor drift during calibration.	The sensor has been rejected during the drift check	• Start a new calibration • If error remains, remembrane the sensor, and start a new calibration. • If error remains, the sensor is defective. Replace with a new one.
Calibration error. Sensor sensitivity error during calibration.	The sensor sensitivity is outside the specifications	• If the sensor has just been remembraned, start a new calibration • Otherwise remembrane the sensor and start a new calibration • Sensor is defective. Replace with a new one.
Calibration error. Sensor temperature error during calibration. This may be due to an error in the sensor module.	The selected sensor temperature value cannot be reached	• Calibrate the sensor • If error remains, the sensor is defective. Replace with a new one.
Calibration required	• The last calibration has been aborted • 12 hours have passed since the last successful calibration • SmartCal has timed out	Perform a calibration

Continued on next page

The TCM4/40 systems, *Continued*

tc error messages – in alphabetical order *(continued)*

Error message	Cause	Recommended action(s)
Communication error. Sensor module disconnected. Call service.	For unknown reasons, the communication between the monitor and the tc module has not been satisfactory	• If error remains, try with another module • If error remains on the new module, contact authorized service personnel
General error. Call service.	The tc module or sensor is not functioning	• Try with another module or sensor • If error remains, contact authorized service personnel
Heater failure	• The measured sensor power is outside the measuring range	• Unplug the sensor from the sensor socket at the rear of the module, and then reconnect it. Calibrate the sensor. • If error remains, the sensor is defective. Replace with a new one.
	The selected sensor temperature cannot be reached	Check if the patient or the surroundings are very cold
Invalid sensor connected	No tcpCO_2/tcpO_2 sensor detected	Change the sensor
No sensor connected	• No sensor detected in the calibration chamber • The sensor in the calibration chamber is not functioning	Connect a functional tcpCO_2/tcpO_2 sensor
pCO_2 out of range	• The measured pCO_2 value is outside the measuring range • The pCO_2 sensor is low on battery power	• Change the membrane • Change the sensor
pO_2 out of range	The measured pO_2 value is outside the measuring range	• Change the membrane • Change the sensor
Site time end	The site time counter has reached zero	• Reposition the sensor on the patient • Recalibrate the sensor

Continued on next page

The TCM4/40 systems, *Continued*

tc error messages – in alphabetical order *(continued)*

Error message	Cause	Recommended action(s)
Temperature failure	• Measured temperature is outside the measuring range • The two sensor thermistors give different temperatures • The sensor temperature is too high	• Calibrate the sensor • If error remains, the sensor is defective. Replace with a new one.
Temperature indication is flashing (*No* text is shown)	The selected sensor temperature has not yet been reached	Wait until it is reached

SpO_2 error messages – in alphabetical order

Error message	Cause	Recommended action(s)
Communication error. SpO_2 module disconnected. Call service.	For unknown reasons, the communication between the monitor and the SpO_2 module has not been satisfactory	• If error remains, try with another module • If error remains on the new module, contact authorized service personnel
General error. Call service.	SpO_2 module or sensor is not functioning	• Try with another module or sensor • If error remains, contact authorized service personnel
No sensor connected	• No SpO_2 sensor connected to the monitor • Invalid sensor connected to the monitor	Connect an SpO_2 sensor to the monitor

Dialog box messages – in alphabetical order

A number of messages (system messages and alerts) appear in dialog boxes.

System message	Cause
Battery level critically low	Less than 5 minutes running time on battery
Battery level is critically low. Setup changes cannot be saved.	The user has made changes in the setup while the battery level was critically low

Continued on next page

The TCM4/40 systems, *Continued*

Dialog box messages – in alphabetical order *(continued)*

System message	Cause
Battery not connected. For data safety reasons, a proper battery must always be connected.	No battery is connected to the monitor
Battery not connected. Setup changes cannot be saved.	The user has made changes in the setup while the battery was not connected
Blood gas setup is only available in measuring mode. You cannot enter this menu.	The user has tried to enter the Blood gas setup while the monitor is not monitoring
Data error. Shut down system immediately.	RAM failure on the PC unit
Data export completed	Export of data to the USB storage device has been completed
Data export failed	Export of data to the USB storage device has failed. E.g. due to missing USB storage device.
Data from more than one patient cannot be selected into a view	The user has tried to load sessions from different patient IDs into a view
Date and time cannot be set during measurement	The user has tried to enter the Date/time setup during measurement
Exporting data. Please wait.	Data is being exported to the USB storage device
Incorrect password. Try again.	The user has tried to enter the Technical setup with an incorrect password
Incorrect time. Try again.	The user has entered an incorrect time
Insert USB storage device	Export to USB port was selected without a memory stick being connected to the USB port
Monitor temperature too high. Please shut down system immediately.	The temperature in the CPU is too high

Continued on next page

The TCM4/40 systems, *Continued*

Dialog box messages – in alphabetical order *(continued)*

System message	Cause
No sessions selected. Select one or more sessions.	The user has tried to view session information (in Patient DMS) without selecting a session
One or more sessions will be deleted from the system. This action cannot be undone.	The user has selected one or more sessions in Patient DMS and pressed ***Delete*** or ***Delete all***
pO_2/pCO_2 not enabled. You cannot enter this menu.	• The pO_2 parameter is disabled in Technical setup, and the user is trying to enter the pO_2 parameter setup • A tcpO_2 sensor is connected, and the user is trying to enter the pCO_2 parameter setup
Saving data. Please wait.	The monitor is saving data before shutting down
The monitor is measuring. Current session cannot be deleted.	The user has tried to delete the session in progress
The monitor is measuring. No other sessions can be loaded into the view.	The user has tried to select one or more sessions – other than the one in progress – into a view
The sensor must be recalibrated if the temperature is changed. Do you want to change the temperature?	The user has tried to change the sensor temperature during Ready or Measuring state

Pure text messages – in alphabetical order

Text message	Cause
Calibrating	The sensor is being calibrated
Ready	The sensor has been calibrated and is ready for use

8. Specifications and ordering information

Specifications

TCM4/40 monitor specifications

Item	Description
Measured parameters	tcpCO_2, tcpO_2, SpO_2, pulse rate and sensor heating power
Display update period	SpO_2 plethysmograph: 25 mm/sec Numerical values: 2 sec pCO_2/pO_2 graphs: 2 sec
Display range	tcpCO_2: 0-200 mmHg or 0.0-26.7 kPa tcpO_2: 0-800 mmHg or 0.0-99.9 kPa SpO_2: 0-100 % Pulse rate: 0 and 20-300 beats per minute (bpm)
Measuring range	tcpCO_2: 5-100 mmHg or 0.7-13.3 kPa tcpO_2: 0-800 mmHg or 0.0-99.9 kPa SpO_2: 70-100 % Pulse rate: 20-250 bpm
Sensor heating power range	10-650 mW ± 3 % of reading (< 10 mW ~ 0 mW)
Temperature settings in °C	37.0-45.0 °C in steps of 0.5 °C
Barometer	Built-in: 375-825 mmHg or 50-110 kPa Accuracy: ±5 mmHg or 0.67 kPa
Calibration	Calibration gas (7.5 % CO_2, 20.9 % O_2, balance N_2)
Ambient relative humidity	20-80 %
Ambient temperature	Monitor: 5-40 °C
	tc sensors: 15-40 °C **NOTICES:** • The ambient temperature must always be at least 3 °C lower than the set sensor temperature. • If SmartCal is selected, the maximum ambient temperature is 34 °C.
	SpO_2 sensors: 5-40 °C
Transport and storage conditions	The monitor and modules can be transported and stored at –20 to +60 °C and < 95 % RH.
Data storage	Up to 48 hours of monitoring data in 2-second data intervals

Continued on next page

Specifications, *Continued*

TCM4/40 monitor specifications *(continued)*

Item	Description		
Computer	Screen: 6½" color touch TFT, full VGA (640 × 480) CPU: AMD ETX LX800, 500 MHz (Pentium Class) Software platform: Windows CE 5.0		
Interface connection	Serial output	EIA232, (RS232)	
	Printer output	USB 2.0 (compliant with USB 1.1)	
	Analog output	0-1 V	
Power supply	100-240 V	50-60 Hz	
Battery	Rechargeable Pb battery	Under normal conditions, the battery can operate for 1 hour before recharging is needed	
Dimensions of monitor	Height: Width: Depth: Weight:	16 cm 30.8 cm 23 cm 4 kg	6.3 in 12.1 in 8.7 in 8.8 lbs
Dimensions of tc module	Height: Width: Depth: Weight:	10.7 cm 14.5 cm 14.8 cm 0.6 kg	4.2 in 5.7 in 5.8 in 1.3 lbs
Dimensions of SpO_2 module	Height: Width: Depth: Weight:	3.5 cm 14.5 cm 14.8 cm 0.21 kg	1.4 in 5.7 in 5.8 in 0.5 lb
Alarm sound pressure	At highest alarm sound level	Alarm tone: Alert tone: End-of-calibration tone:	83 dBA 73 dBA 64 dBA
	At lowest alarm sound level	Alarm tone: Alert tone: End-of-calibration tone:	65 dBA 58 dBA 51 dBA

Continued on next page

Specifications, *Continued*

EMC approvals and compliance

The monitor is intended for use in the electromagnetic environment specified in the tables below. The customer or user of the monitor should assure that it is used in such an environment. The monitor complies with IEC 60601-1-2.

Guidance and manufacturer's declaration – electromagnetic emissions

Emissions test	Compliance	Electromagnetic environment guidance
RF emissions CISPR 11	Group 1	The monitor's RF emissions are very low and they are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The monitor is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	N/A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	N/A	

Guidance and manufacturer's declaration – electromagnetic immunity

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial and/or hospital environment
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial and/or hospital environment

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Specifications, *Continued*

EMC approvals and compliance *(continued)*

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment guidance
Voltage dips, short interruptions, and voltage variations on power supply input lines IEC 61000-4-11	< 5 % U_T (> 95 % drop in U_T) for 0.5 cycle 40 % U_T (60 % drop in U_T) for 5 cycles 70 % U_T (30 % drop in U_T) for 25 cycles < 5 % U_T (> 95 % drop in U_T) for 5 seconds	N/A, as the monitor has battery backup	None
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	None
NOTICE: U_T is the AC mains voltage prior to application of the test level.			

Continued on next page

Specifications, *Continued*

EMC approvals and compliance *(continued)*

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the monitor, including cables, than the recommended separation distance calculated from the equation appropriate for the frequency of the transmitter. **Recommended separation distance** $d = 1.2\sqrt{P}$ 150 kHz to 80 MHz $d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz where P is the output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a], should be less than the compliance level in each frequency range[b]. Interference may occur in the vicinity of equipment marked with the following symbol: 
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the monitor is used exceeds the applicable RF compliance level above, the monitor should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the monitor.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

NOTICES:

- At 80 MHz and 800 MHz, the higher frequency range applies.
- These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Continued on next page

Specifications, *Continued*

EMC approvals and compliance *(continued)*

Recommended separation distances between portable and mobile RF communications equipment and the TCM monitor

The monitor is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or user of the monitor can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the monitor as recommended below, according to the maximum output power of the communications equipment.

Rated output power of transmitter Watts	**Separation distance according to frequency of transmitter in meters**		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	**80 MHz to 800 MHz** $d = 1.2\sqrt{P}$	**800 MHz to 2.5 GHz** $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at an output power not listed above, the recommended separation distance *d* in meters can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in the corresponding column.

NOTICES:

- At 80 MHz and 800 MHz, the higher frequency range applies.
- These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Other approvals and compliance

Item	**Description**
Patient safety	• The instrument complies with IEC 60601-1 and IEC 60601-2-23. • The following test house has approved the instrument: CSA in Canada according to CAN/CSA-C22.2 No. 601.1-M90, 601.1S1-94, 601.1B-98, 601.2.23-02 and UL std. No. 60601-1.

Continued on next page

Specifications, *Continued*

Other approvals and compliance *(continued)*

Item	Description
Compliance	The monitor complies with: • IEC-60601-1, Medical Electrical Equipment – Part 1: General requirements for safety • IEC-60601-1-2, Medical Electrical Equipment – Part 1-2: General requirements for safety. Collateral standard: Electromagnetic compatibility - requirements and tests • IEC-60601-1-4, General requirements for safety and design of programmable electrical medical systems • IEC-60601-2-23, Medical Electrical Equipment – Part 2-23: Particular requirements for the safety, including essential performance, of transcutaneous partial pressure monitoring equipment • IEC-60601-2-49, Medical Electrical Equipment – Part 2-49: Particular requirements for the safety of multifunction patient monitoring equipment. • IEC-60601-3-1, Medical Electrical Equipment – Part 3-1: Essential performance requirements for transcutane-ous oxygen and carbon dioxide partial pressure monitoring equipment • ISO 9919, Medical Electrical Equipment. Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use • IEC-60601-1-8, Medical Electrical Equipment – Part 1-8: General requirements for safety. Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems • Class II Special Controls Guidance Document: Cutaneous Carbon Dioxide (tc*p*CO_2) and Oxygen (tc*p*O_2) Monitors; Guidance for Industry and FDA (December 13, 2002) • Draft Guidance for Industry and Staff: Pulse oximeters premarket notifications submissions [510(k)s]
pCO_2	**Non-linearity and hysteresis:** The requirement to non-linearity and hysteresis (±5 mmHg) is fulfilled for gas concentrations between 5 % and 10 % CO_2. **Drift:** The requirement to drift ≤ 10 % of initial reading over the calibration interval is fulfilled.

Continued on next page

Specifications, *Continued*

Other approvals and compliance *(continued)*

Item	Description
pCO_2 *(continued)*	The following drift per hour has been measured at a sensor temperature of 43 °C: Max. drift per hour at 5 % CO_2: 2 % Max. drift per hour at 10 % CO_2: 2 % Calibration interval: 4 hours **Accuracy:** The device indicates the partial pressure of carbon dioxide (cutaneous pCO_2) to within 5 mmHg over the measurement range. **Response time (10 % to 90 % response):** The following max. response times have been measured at a sensor temperature of 43 °C: E5280/E5260: 26 seconds E5480: 83 seconds
pO_2	**Non-linearity and hysteresis:** The requirement to non-linearity and hysteresis (±5 mmHg) is fulfilled for gas concentrations between 2 % O_2 and 20.9 % O_2. **Drift:** The requirement to drift ≤ 5 % of initial reading over the calibration interval is fulfilled. The following drift per hour has been measured at a sensor temperature of 43 °C: Max. drift per hour at 10 % O_2: 1 % Max. drift per hour at 20.9 % O_2: 1 % Calibration interval: 4 hours **Accuracy:** The device indicates the partial pressure of oxygen (cutaneous pO_2) to within 5 mmHg over the range from 0 % O_2 to 20.9 % O_2. In the range from 20.9 % O_2 to full scale, the accuracy is better than ±10 %. **Response time (10 % to 90 % response):** The following max. response times have been measured at a sensor temperature of 43 °C: E5280: 18 seconds E5480: 26 seconds

Continued on next page

Specifications, *Continued*

Other approvals and compliance *(continued)*

Item	Description
SpO_2	**Accuracy over 70 % to 100 %:** Sensor model: Weight range: Accuracy: DS100A > 40 kg ±3 % SpO_2 Oxiband A/N (adults) > 40 kg ±3 % SpO_2 Oxiband A/N (neonates) < 3 kg ±4 % SpO_2 Oxiband P/I 3-40 kg ±3 % SpO_2 **Test considerations and oximeter accuracy – Functional testers and patient simulators** Some models of commercially available bench top functional testers and patient simulators can be used to verify the proper functionality of Nellcor pulse oximeter sensors, cables and monitors. See the individual testing device's operator's manual for the procedures specific to the model of tester being used. While such devices may be useful for verifying that the pulse oximeter sensor, cable and monitor are functional, they are incapable of providing the data required to properly evaluate the accuracy of a system's SpO_2 measurements. Fully evaluating the accuracy of the SpO_2 measurements requires, at a minimum, accommodating the wavelength characteristics of the sensor and reproducing the complex optical interaction of the sensor and the patient's tissue. These capabilities are beyond the scope of known bench top testers, including known devices which claim to measure sensor LED wavelength. SpO_2 measurement accuracy can only be evaluated in vivo by comparing pulse oximeter readings with values traceable to SaO2 measurements obtained from simultaneously sampled arterial blood using a laboratory CO-oximeter. Many functional testers and patient simulators have been designed to interface with the pulse oximeter's expected calibration curves and may be suitable for use with Nellcor monitors and/or sensors. Not all such devices, however, are adapted for use with the Nellcor *OXIMAX* digital calibration system. While this will not affect use of the simulator for verifying system functionality, displayed SpO_2 measurement values may differ from the setting of the test device. For a properly functioning monitor, this difference will be reproducible over time and from monitor to monitor within the performance specifications of the test device.
Pulse	**Accuracy:** ±3 bpm over 20-250 bpm range

Continued on next page

Specifications, *Continued*

Other approvals and compliance *(continued)*

Item	Description
Known sources of interference	**tc*p*CO_2/tc*p*O_2:** After an hour's exposure, halothane (4 % evaporated into carrier gas) will interfere with the tc*p*O_2 readings of the sensor and thereby also influence the combined effects of non-linearity and hysteresis (beyond ±6 mmHg/±0.8 kPa). Furthermore, if the patient is treated with Halothane, this may cause changes in the skin blood flow and in this way interfere with the tc*p*O_2 readings. Halothane does *not* affect the tc*p*CO_2 readings. The following substances have been tested and shown not to influence the combined effects of non-linearity and hysteresis (within ±6 mmHg/±0.8 kPa): • Nitrous oxide (in a gas mixture of 60 % N_2O, 5 % CO_2, 20.9 % O_2, balance N_2). In the following referred to as carrier gas. • Enflurane: 5 % evaporated into carrier gas. • Isoflurane: 5 % evaporated into carrier gas. • Sevoflurane: 5 % evaporated into carrier gas. • Desflurane: 12 % evaporated into carrier gas. **SpO_2:** Inaccurate measurements can be caused by: • prolonged patient movement • venous pulsations • intravascular dyes, such as indocyanine green or methylene blue • defibrillation • incorrect application of the sensor • placement of the sensor on an extremity with a blood pressure cuff, arterial catheter or intravascular line • ambient light Loss-of-pulse signal can occur for the following reasons: • The sensor is applied too tightly • A blood pressure cuff is inflated on the same extremity as the one with the sensor attached • There is arterial occlusion proximal to the sensor

Continued on next page

Specifications, *Continued*

Other approvals and compliance *(continued)*

Item	Description
Biocompatibility	**Fixation ring:** The suitability of the fixation ring adhesives for use on intact human skin is supported by a series of in vitro and in vivo evaluations. The fixation ring adhesives meet the requirements of ISO 10993-1, "Biological Evaluation of Medical Devices. Part 1: Evaluation and Testing" for surface devices contacting intact human skin. The evaluations include cell cytotoxicity, skin irritation and sensitization potential. **Nellcor SpO_2 sensors (TCM40 only):** The sensors have passed the recommended biocompatibility testing and are therefore in compliance with ISO 10993-1.

Patents

One or more of the following patents and patent applications may apply:

- US Patent No.: US7,474,908
- US Patent Application No.: US2007/0238943
- European Patent Application Nos.: EP1753343, EP2007272
- Japanese Patent Application No.: JP2007/537799
- Chinese Patent Application No.: CN1988849
- International Patent Application No.: WO2007/115568

Other patents pending

Materials and accessories

Item	Description
All materials and accessories	All materials and accessories are latex-free

E5480 sensor

Item	Description		
Dimensions	Diameter:		
	• Sensor housing:	15 mm	0.6 in
	• Silver body:	8.1 mm	0.32 in
	Height:	7.81 mm	0.3 in
	Weight:	2.6 g	0.08 oz
Sensor cable	Length:	2.25 m	88.6 in

Continued on next page

Specifications, *Continued*

E5280 and E5260 sensors

Item	Description		
Dimensions	Diameter:		
	• Sensor housing:	15 mm	0.6 in
	• Silver body:	9.1 mm	0.36 in
	Height:	11.3 mm	0.44 in
	Weight:	2.9 g	0.1 oz
Sensor cable	Length:	2.25 m	88.6 in

OxiMax sensors

Item	Description
Dissipation	52.5 mW
Wavelength	The wavelength range of the light emitted is near 660 nm and 890 nm.

Accessories

TCM4/40 systems accessories

Description	Code no.
E5480 tc*p*CO_2/tc*p*O_2 sensor (tinyTeddy)	945-660
E5280 tc*p*CO_2/tc*p*O_2 sensor	945-377
E5260 tc*p*CO_2 sensor	945-655
Membraning kit for E5480 sensor, containing: • tc*p*CO_2/tc*p*O_2 electrolyte solution • 10 membraning tools • Cleaning paper, bag with 5 pieces	905-805
Membraning kit for E5280 and E5260 sensors, containing: • tc*p*CO_2/tc*p*O_2 electrolyte solution • 12 green membrane units with PP membrane • O-ring remover key • Cleaning paper, bag with 20 pieces	904-892
Fixation kit for E5480 sensor, containing: • 4 × 25 disposable fixation rings • 4 × 20 mL contact liquid	905-836
Fixation kit for E5280 and E5260 sensors, containing: • 4 × 25 disposable fixation rings • 4 × 20 mL contact liquid	904-891
Large fixation ring for E5480 tc*p*CO_2/tc*p*O_2 sensor (tinyTeddy)	905-901

SpO_2 starter kits

Description	Code no.
SpO_2 module with Nellcor DS100A sensor	902-876
SpO_2 module with Nellcor Oxiband A/N sensor	902-877
SpO_2 module with Nellcor Oxiband P/I sensor	902-878
SpO_2 module without sensor	902-946

TCM4/40 documentation

Item	Code no.
TCM4/40 operator's manual, English	990-277

Continued on next page

Accessories, *Continued*

Line cords

Description	Code no.
Line cord 120 V, USA and JPN	615-407
Line cord 230 V, UK	615-312
Line cord 230 V, ITA	615-313
Line cord 230 V, ISR	615-315
Line cord 230 V, other 230 V countries	615-303
Line cord 230 V, AUS and NZA	615-317
Line cord 230 V, ZAF and IND	615-318

Additional items

Description	Code no.
Extension cable for tc*p*CO_2/tc*p*O_2 sensor, 3 m (118.1 in)	617-853
Extension cable for tc*p*CO_2/tc*p*O_2 sensor, 6 m (236.2 in)	617-864
TCM4xx ETX Serial Adapter	636-649
TCM4xx ETX Analog Adapter	636-650
TCM4xx ETX VueLink Adapter	636-651
tc*p*CO_2/tc*p*O_2 module	902-778
Calibration chamber gasket for E5480 sensor	837-488
Calibration chamber gasket for E5280 and E5260 sensors	837-159
CAL1 standard calibration gas: 7.5 % CO_2, 20.9 % O_2, balance N_2, 180 mL	962-187
CAL1 standard calibration gas: 7.5 % CO_2, 20.9 % O_2, balance N_2, 180 mL (US and Canada)	962-188
CAL2 standard calibration gas: 10 % CO_2, balance N_2, 999 mL **NOTICE:** Not applicable in Germany.	962-096
CAL2 standard calibration gas: 10 % CO_2, 1 L **NOTICE:** Only applicable in Germany.	962-154
Valve key (for CAL2 gas)	922-509
Gas adapter (for CAL2 gas)	847-398
Gasket for adapter (847-398)	837-487
12 V 2AH lead-acid battery	431-018

9. Functional description

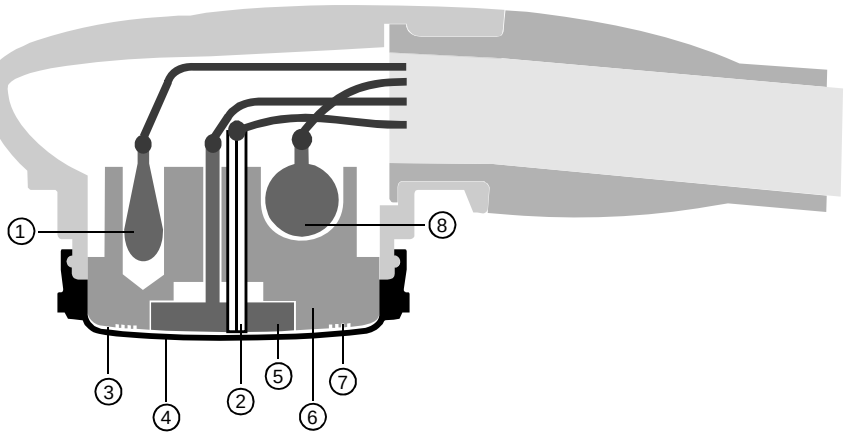
tc*p*CO_2/tc*p*O_2 measurement

Construction of sensors

Sensor components

The tcpCO_2/tcpO_2 sensors (E5480 and E5280) combine a heating element, two temperature sensors, a Clark-type oxygen electrode, and a Severinghaus-type carbon dioxide electrode in a single unit.

E5480 sensor components

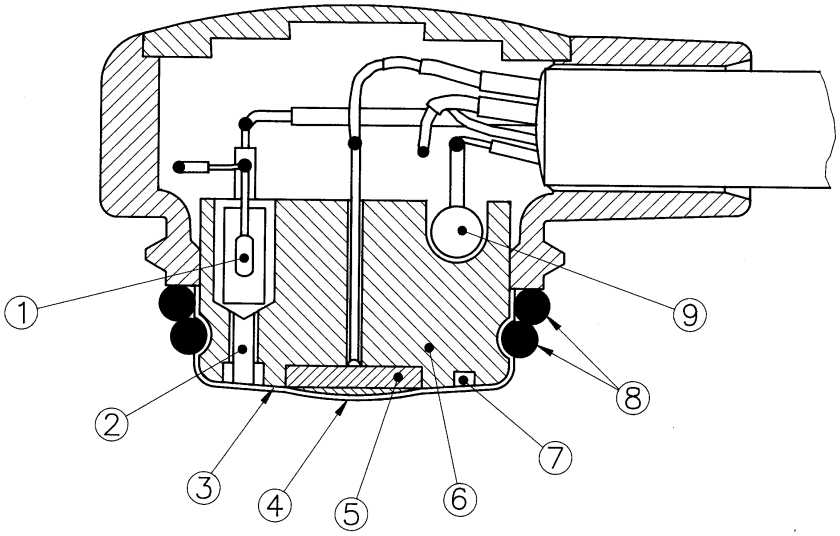


Number	Component
1	NTC resistors – temperature sensors
2	Platinum cathode (pO_2 part)
3	Electrolyte covering the sensor surface
4	CO_2/O_2-permeable membranes
5	Reinforced solid-state glass electrode (pCO_2 part)
6	Ag/AgCl reference electrode
7	Electrolyte reservoir
8	Heating element

Continued on next page

Construction of sensors, *Continued*

E5280 sensor components



NOTICE: The single tcpCO_2 sensor (E5260) is identical to the tcpCO_2/tcpO_2 sensor (E5280) except that it does not contain an active platinum cathode (the pO_2 part).

Number	Component
1	NTC resistors – temperature sensors
2	Platinum cathode (pO_2 part)
3	Electrolyte covering the sensor surface
4	CO_2/O_2-permeable membranes
5	Reinforced solid-state glass electrode (pCO_2 part)
6	Ag/AgCl reference electrode
7	Electrolyte reservoir
8	O-rings to secure the membranes
9	Heating element

NTC resistors

The temperature of the sensor is measured by the NTC resistors incorporated in the Ag/AgCl reference electrode. Due to the high thermal conductivity of the silver body, the NTC resistors respond quickly to any changes in temperature. The thermostatting system will keep the sensor at the preset temperature.

Local vasodilation

When the sensor is attached to the skin, the generated heat is transferred from the heating element via the silver body to the skin surface. The heat produces local vasodilation and increases the permeability of the skin to oxygen and carbon dioxide, thus making a measurement on the skin surface possible.

pCO_2 measuring principle

Definition

The measurement of *p*CO_2 is defined as the partial pressure (or tension) of carbon dioxide. It is performed by means of a Stow-Severinghaus electrode based on an electrochemical electrode chain consisting of a pH glass electrode (the sensor electrode) and a silver chloride reference electrode.

Measuring principle

As CO_2 is released from the skin, it diffuses through the membrane into the electrolyte, where it reacts with water forming carbonic acid, which immediately dissociates into HCO_3^- and H^+ according to the following equation:

$$H_2O + CO_2 \rightleftarrows H_2CO_3 \rightleftarrows H^+ + HCO_3^-$$

The changes in H^+ in the electrolyte imply changes in pH.

As the pH in the electrolyte changes, the voltage between the glass electrode and the reference electrode changes. The pH change is converted to a *p*CO_2 reading on the basis of the linear relationship between pH and log *p*CO_2, as expressed by the Henderson-Hasselbalch equation:

$$pH = pK + \log \frac{\left[HCO_3^-\right]}{a \times pCO_2}$$

where

pK = dissociation constant of carbonic acid

$\left[HCO_3^-\right]$ = concentration of HCO_3^-

a = solubility coefficient of dissolved CO_2

pCO_2 = partial pressure of CO_2

As no charged molecules can penetrate the membrane, the change in pH is strictly due to the carbon dioxide diffusion into the electrolyte.

The potential measured across the combined electrode chain is fed into the *p*CO_2 channel, where it is digitized. The digitized signal is then passed on to the microcomputer, where it is converted to display *p*CO_2 in mmHg or kPa.

The monitor is based on a microcomputer system in which all data obtained by the sensor are collected, processed and compared with the alarm limits preselected in the monitor's setup programs prior to presentation on the screen.

Severinghaus temperature correction

In most clinical settings, transcutaneous *p*CO_2 monitoring is performed using the Severinghaus temperature correction factor.

This means that the tc*p*CO_2 readings are corrected to 37 °C (normal body temperature), using the following formula:

$$tcpCO_2(T) = pCO_2(37\ °C) \times 10^{-0.019(T - 37\ °C)}$$

where T is the set sensor temperature (°C).

pO_2 measuring principle

Definition

The measurement of pO_2 is defined as the partial pressure (or tension) of oxygen. It is performed as a direct polarographic measurement based on an electrochemical electrode chain consisting of the platinum cathode (the sensor electrode) and the silver anode (the reference electrode).

Measuring principle

The sensor tip is covered with a thin membrane which stabilizes the conditions of pO_2 diffusion to the sensor. Oxygen diffuses through this membrane to the cathode where a reduction of oxygen occurs as a result of the current-generating process:

$$O_2 + 2H_2O + 4e^- \rightleftarrows 4OH^-$$

At the anode the following reaction takes place:

$$4Ag + 4Cl^- \rightarrow 4AgCl + 4e^-$$

The reduction of oxygen at the platinum cathode generates a current, which is fed into the pO_2 channel, where it is converted into a voltage and digitized. This digitized signal is then passed on to the microcomputer, where it is reconverted to display pO_2 in mmHg or kPa.

Calibration of sensor

Temperature-corrected pCO_2 values

In order for the calibration value to be within the normal physiological range for tcpCO_2, Radiometer uses a 7.5 % CO_2 concentration in the calibration gas for the TCM4/40 monitors.

The 7.5 % CO_2 calibration gas will give the following CO_2 calibration value (at a barometric pressure of 760 mmHg):

$$pCO_2(CAL) = B \times \frac{\%\ CO_2}{100} = 760 \times \frac{7.5}{100} = 57\ \text{mmHg}$$

When the Severinghaus temperature correction factor is activated (Severinghaus corr. "ON"), the above pCO_2 calibration value will result in the following temperature-corrected pCO_2 values:

Sensor temp °C	37	38	39	40	41	42	43	44	45
Temperature corr. factor	1.00	1.04	1.09	1.14	1.19	1.24	1.30	1.36	1.42
Temperature corr. value, mmHg*	57	55	52	50	48	46	44	42	40

* Temperature corr. pCO_2 value = $\frac{57}{\text{Temp. corr. factor}}$

Temp.corr.factor = $10^{-0.019(T-37\ °C)}$

Gas calibration values

The monitor calculates the nominal dry gas tcpCO_2 calibration values relative to the barometric pressure in accordance with the following formula:

$$pCO_2(CAL) = B \times \frac{\%CO_2}{100}$$, where

B = the barometric pressure in mmHg or kPa

% CO_2 = the percentage of CO_2 in the calibration gas (i.e. 7.5 %)

The monitor calculates the nominal dry gas tcpO_2 calibration values relative to the barometric pressure in accordance with the following formula:

$$pO_2(CAL) = B \times \frac{\%O_2}{100}$$, where

B = the barometric pressure in mmHg or kPa

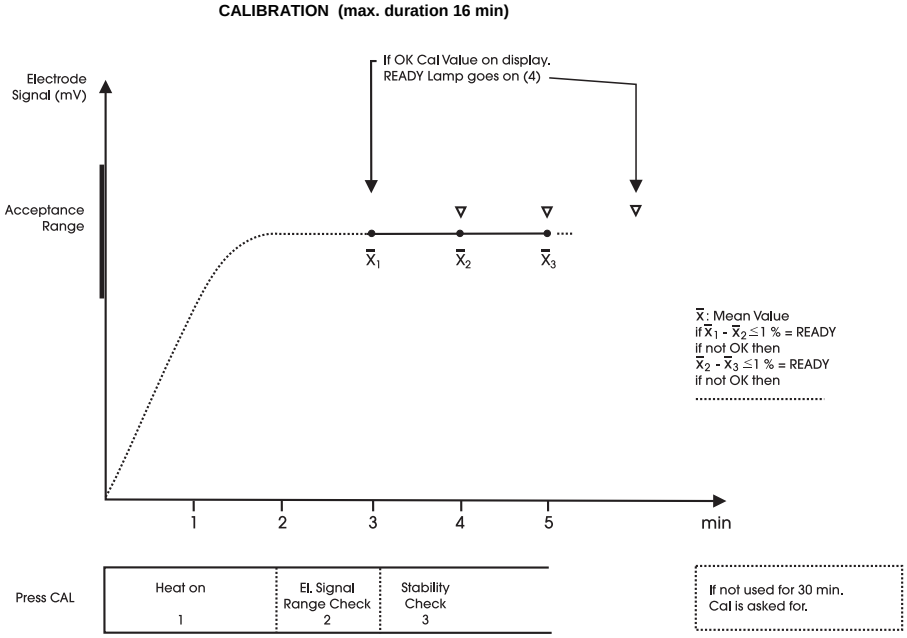
% O_2 = the percentage of O_2 in the calibration gas (i.e. 20.9 %)

Continued on next page

Calibration of sensor, *Continued*

Calibration process

The calibration process includes the stages described in the table below:



Stage	Description
Heating	The sensor is typically heated to the preset temperature within one minute. If it has not reached this temperature within three minutes, the computer will reject the sensor, and the error message "Calibration error. Sensor temperature error during calibration." will be displayed.
Check of sensor signal range	When the sensor reaches the preset temperature, the monitor checks the sensor pCO_2 and pO_2 signals. If these are not within a specified range within one minute, the monitor rejects the sensor, and the error message "Calibration error. Sensor sensitivity error during calibration." will be displayed. **NOTICE:** The sensor may also be rejected because of an incorrect calibration value.
Check of stability	After heating and acceptance of the sensor signal range, the monitor checks the sensor stability for maximum 10 minutes or until the change in the sensor signal is below 1 % compared with the signals registered one minute earlier. If, following this, the stability criterion is still not fulfilled, the monitor will reject the sensor, and the error message "Calibration error. Sensor drift during calibration." will be displayed. If the stability is accepted, the monitor will then display "Ready".

Continued on next page

Calibration of sensor, *Continued*

Patient safety

In order to satisfy the requirements for patient safety, the circuitry that is interconnected with the sensor is galvanically insulated from the rest of the system.

The monitor is equipped with an extensive safety system for controlling and monitoring sensor temperature.

- The microprocessor program gives an audiovisual alert if the sensor temperature deviates ±0.3 ºC from the preset value.
- The sensor power consumption is permanently supervised. If it exceeds maximum effect for more than two minutes, the heat switches off.
- If the sensor temperature reaches 46 ºC or falls below 5 ºC, this could indicate a short or an open circuit in the thermostatting control loop. In this case, the monitor utilizes one of several hardware and software controls to immediately and permanently switch off the sensor heating.
- If there is a temperature difference of more than 0.6 ºC between the two thermistors, heating switches off immediately and permanently.
- If a software error occurs, a "watchdog" circuit in the monitor immediately and permanently switches off the sensor heating.

Solutions and calibration gases

Solutions

The following solutions are used with the TCM4/40 systems:

Solution	Description	
tc*p*CO_2/tc*p*O_2 electrolyte solution, 10 mL	Use:	To be applied on the clean sensor surface.
	Composition:	1,2-propanediol, propanetriol, potassium chloride, potassium hydrogen carbonate and deionized water.
	Storage:	At room temperature or below.
	Stability:	Expiration date and lot no. are printed on a separate label on the bottle.
Contact liquid, 20 mL	Use:	To establish contact between the skin and the sensor during in vivo measurements.
	Composition:	1,2-propanediol and deionized water.
	Storage:	At room temperature or below.
	Stability:	Expiration date and lot no. are printed on a separate label on the bottle.

NOTICE: Keep the bottle caps on when bottles are not in use.

Calibration gases

- CAL1 standard calibration gas (7.5 % CO_2, 20.9 % O_2 with N_2 as balance)
- CAL2 standard calibration gas (10 % CO_2 with N_2 as balance)

WARNING – *Risk of explosion*
Calibration gas cylinder: Contents under pressure. Do not puncture. Do not use or store near heat or open flame. Exposure to temperatures above 54 °C (for CAL2) and 50 °C (for CAL1) may cause contents to vent or cause bursting. Never discard container into fire or incinerator as it may cause an explosion.

WARNING – *Risk of explosion*
Before discarding an empty CAL2 gas cylinder, remove the safety valve using the valve key (code no. 922-509). If you do not do this, the calibration gas cylinder may burst if exposed to heat.

Traceability certificates

Certificate of Traceability

Product name: CAL1 standard calibration gas

Type: 7.5 % CO_2, 20.9 % O_2, balance N_2, 180 mL

Code: 962-187

Traceability of parameters:

Parameter	Unit	Traceable to	Expanded Uncertainty
CO_2	mol %	Primary, gravimetrically prepared standards. Traceable to NIST traceable weights.	±0.07
O_2	mol %	Primary, gravimetrically prepared standards. Traceable to NIST traceable weights.	±0.03

Certification: Each lot of this product has been tested, and the nominal values, specified on the label of this product, have been established with the above traceability.

Bjarne Kristensen

H.B. Kristensen
Head of Chemical Reference Laboratory

The traceability of the above parameters is fully described in booklet AS 117: *Traceability to the Primary Reference Standards at Radiometer*, available from Radiometer.

RADIOMETER COPENHAGEN

Certificate of Traceability

Product name: CAL1 standard calibration gas (US and Canada)

Type: 7.5 % CO_2, 20.9 % O_2, balance N_2, 180 mL

Code: 962-188

Traceability of parameters:

Parameter	Unit	Traceable to	Expanded Uncertainty
CO_2	mol %	Primary, gravimetrically prepared standards. Traceable to NIST traceable weights.	±0.07
O_2	mol %	Primary, gravimetrically prepared standards. Traceable to NIST traceable weights.	±0.03

Certification: Each lot of this product has been tested, and the nominal values, specified on the label of this product, have been established with the above traceability.

Bjarne Kristensen

H.B. Kristensen
Head of Chemical Reference Laboratory

The traceability of the above parameters is fully described in booklet AS 117: *Traceability to the Primary Reference Standards at Radiometer*, available from Radiometer.

NOTICE: The below-mentioned CAL2 calibration gas is not applicable to Germany. For information on the CAL2 calibration gas that applies to Germany, see next page.

Certificate of Traceability

Product name: CAL2 standard calibration gas

Type: 10 % CO_2, balance N_2, 999 mL

Code: 962-096

Traceability of parameters:

Parameter	Unit	Traceable to	Expanded Uncertainty
CO_2	mol %	Primary, gravimetrically prepared standards. Traceable to NIST traceable weights.	±0.02
O_2	mol %	Primary, gravimetrically prepared standards. Traceable to NIST traceable weights.	±0.03

Certification: Each lot of this product has been tested, and the nominal values, specified on the label of this product, have been established with the above traceability.

Bjarne Kristensen

H.B. Kristensen
Head of Chemical Reference Laboratory

The traceability of the above parameters is fully described in booklet AS 117: *Traceability to the Primary Reference Standards at Radiometer*, available from Radiometer.

NOTICE: The below-mentioned CAL2 calibration gas applies to Germany only.

Certificate of Traceability

Product name: Cal 2 Gas, 10 % CO_2

Type: Gas mixture, 1 L

Code: 962-154

Traceability of parameters:

Parameter	Unit	Traceable to	Expanded Uncertainty
CO_2	mol %	Primary, gravimetrically prepared standards. Traceable to NIST traceable weights.	0.02
O_2	mol %	Primary, gravimetrically prepared standards. Traceable to NIST traceable weights.	0.02

Certification: Each lot of this product has been tested, and the nominal values, specified on the label of this product, have been established with the above traceability.

Bjarne Kristensen

H.B. Kristensen
Head of Chemical Reference Laboratory

The traceability of the above parameters is fully described in booklet AS 117: *Traceability to the Primary Reference Standards at Radiometer*, available from Radiometer.

RADIOMETER COPENHAGEN

Pulse oximetry measurement

Measuring principle

Introduction

The monitor uses pulse oximetry to measure functional oxygen saturation in the blood. Pulse oximetry works by applying a sensor to a pulsating arteriolar vascular bed, such as a finger or toe. The sensor contains a dual light source and a photodetector.

Bone, tissue, pigmentation and venous vessels normally absorb a constant amount of light over time. The arteriolar bed normally pulsates and absorbs variable amounts of light during the pulsations. The ratio of light absorbed is translated into a measurement of functional oxygen saturation (SpO_2).

Because a measurement of SpO_2 is dependent upon light from the sensor, excessive ambient light can interfere with this measurement.

Specific information about ambient conditions, sensor application and patient conditions is contained throughout this manual.

Measuring principles

Pulse oximetry is based on two principles: that oxyhemoglobin and deoxyhemoglobin differ in their absorption of red and infrared light (spectrophotometry), and that the volume of arterial blood in tissue (and hence, light absorption by that blood) changes during the pulse (plethysmography). A pulse oximeter determines SpO_2 by passing red and infrared light into an arteriolar bed and measuring changes in light absorption during the pulsatile cycle. Red and infrared low-voltage light-emitting diodes (LED) in the oximetry sensor serve as light sources; a photodiode serves as the photodetector.

NOTICE: Information about the range of wavelength can be useful to clinicians in particular. For information on the range of wavelength, see *OxiMax sensors* in the section *Specifications* in chapter 8.

Because oxyhemoglobin and deoxyhemoglobin differ in light absorption, the amount of red and infrared light absorbed by blood is related to hemoglobin oxygen saturation. To identify the oxygen saturation of arterial hemoglobin, the monitor uses the pulsatile nature of arterial flow. During systole, a new pulse of arterial blood enters the vascular bed, and blood volume and light absorption increase.

During diastole, blood volume and light absorption reach their lowest point. The monitor bases its SpO_2 measurements on the difference between maximum and minimum absorption (measurements at systole and diastole). By doing so, it focuses on light absorption by pulsatile arterial blood, eliminating the effects of non-pulsatile absorbers such as tissue, bone and venous blood.

Oxygen saturation vs oxyhemoglobin fraction

The monitor measures oxygen saturation, also called functional saturation (oxygenated hemoglobin expressed as a percentage of the hemoglobin that can transport oxygen). It does not detect significant amounts of dysfunctional hemoglobin, such as carboxyhemoglobin or methemoglobin. To compare oxygen saturation measurements with those from an instrument that measures oxyhemoglobin fraction, also erroneously called fractional saturation (oxygenated hemoglobin expressed as a percentage of all measured hemoglobin, including measured dysfunctional hemoglobins), oxyhemoglobin fraction must be converted as follows:

$$\text{oxygen saturation} = \frac{\text{oxyhemoglobin fraction}}{100 - (\%\ \text{carboxyhemoglobin} + \%\ \text{methemoglobin})} \times 100$$

Calibration of sensor

Description

Because light absorption by hemoglobin is wavelength dependent and because the mean wavelength of LEDs varies, an oximeter must know the mean wavelength of the sensor's red LED to accurately measure SpO_2.

During monitoring, the monitor's software selects coefficients that are appropriate for the wavelength of that individual sensor's red LED; these coefficients are then used to determine SpO_2.

Additionally, to compensate for differences in tissue thickness, the light intensity of the sensor's LEDs is adjusted automatically.

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Date of issue

Radiometer representative:

If you have any questions or need assistance, please contact your local Radiometer representative.

Manufacturer:

RADIOMETER

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TCM4/40 monitoring systems operator's manual

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